BEFORE THE

INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION: STANFORD UNIVERSITY
PAUL BERG HALL
LI KA SHING LEARNING CENTER
290 CAMPUS DRIVE
STANFORD, CALIFORNIA

DATE: THURSDAY, AUGUST 25, 2011
9 A.M.

REPORTER: BETH C. DRAIN, CSR
CSR. NO. 7152

BRS FILE NO.: 89090

I N D E X

STANFORD, CALIFORNIA; THURSDAY, AUGUST 25, 2011

9 A.M.

CHAIRMAN THOMAS: CAN EVERYBODY TAKE THEIR SEAT, PLEASE?

MEMBERS OF THE BOARD, STAFF, MEMBERS OF THE PUBLIC, WOULD LIKE TO WELCOME YOU TO THE BEAUTIFUL STANFORD CAMPUS AND CALL TO ORDER THE AUGUST 25TH MEETING OF THE ICOC. I'D LIKE TO THANK, BEFORE WE GET STARTED HERE, JENNIFER PRYNE, DOUG GUILLEN, AND MELISSA KING, AS ALWAYS, FOR SETTING UP THE MEETING HERE SO THAT WE CAN HOLD IT IN A SEAMLESS AND PROFESSIONAL MANNER. SO THANK YOU VERY MUCH TO ALL OF YOU FOR YOUR HARD WORK.

MELISSA, WOULD YOU LEAD US IN THE PLEDGE OF ALLEGIANCE FOLLOWED BY ROLL CALL.

(THE PLEDGE OF ALLEGIANCE.)

MS. KING: ROBERT BIRGENEAU. FLOYD BLOOM. GARY FIRESTEIN FOR DAVID BRENNER.

DR. FIRESTEIN: HERE.

MS. KING: SUSAN BRYANT.

DR. BRYANT: HERE.

MS. KING: MARCY FEIT. MICHAEL FRIEDMAN. LEEZA GIBBONS.

MS. GIBBONS: HERE.

MS. KING: MICHAEL GOLDBERG.
MR. GOLDBERG: HERE.
MS. KING: SAM HAWGOOD.
DR. HAWGOOD: HERE.
MS. KING: STEPHEN JUELSGAARD.
DR. JUELSGAARD: HERE.
MS. KING: SHERRY LANSING.
MS. LANSING: HERE.
MS. KING: TED LOVE.
DR. LOVE: HERE.
MS. KING: BERTRAM LUBIN. LEON FINE FOR SHLOMO MELMED.
DR. FINE: HERE.
MS. KING: PHIL PIZZO.
DR. PIZZO: HERE.
MS. KING: CLAIRE POMEROY.
DR. POMEROY: HERE.
MS. KING: FRANCISCO PRIETO.
DR. PRIETO: HERE.
MS. KING: ELIZABETH FINI FOR CARMEN PULIAFITO.
DR. FINI: HERE.
MS. KING: ROBERT QUINT. DUANE ROTH.
MR. ROTH: HERE.
MS. KING: JOAN SAMUELSON. DAVID

SERRANO-SEWELL. JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. KING: JONATHAN SHESTACK. OSWALD STEWARD.

DR. STEWARD: HERE.

MS. KING: ART TORRES.

MR. TORRES: HERE.

MS. KING: KRISTINA VUORI.

DR. VUORI: HERE.

MS. KING: JAMES ECONOMOU FOR EUGENE WASHINGTON.

DR. ECONOMOU: HERE.

MS. KING: JON THOMAS.

CHAIRMAN THOMAS: YES, I'M HERE TOO.

AS USUAL, BY THE WAY, FOR MEMBERS OF THE PUBLIC, WE ARE HAVING A SIMULTANEOUS WEBCAST OR, AS CHICK HEARN USED TO SAY, A SIMULCAST SO THAT THE PUBLIC ALL AROUND THE WORLD AND VIA THE INTERNET CAN SHARE IN THESE PROCEEDINGS.

WOULD LIKE TO WELCOME DRS. FINE AND FIRESTEIN TO THEIR FIRST MEETING. WELCOME. WE JUST HAD AN OFFICIAL SWEARING IN CEREMONY OVER THERE. AND DELIGHTED TO HAVE YOU HERE ALONG WITH THE REST OF THE BOARD.

BEGIN HERE WITH A CHAIR REPORT, WHICH WILL

BE SHORT, BUT A LITTLE LONGER THAN NORMAL AS THIS IS MY FIRST MEETING AS CHAIR JUST TO GIVE YOU A REPORT OF WHAT'S BEEN GOING ON. WE ENTERED THIS LAST COUPLE OF MONTHS WHEN I BEGAN MY TENURE IN AN ATMOSPHERE OF CONSIDERABLE FISCAL CRISIS AT THE STATE. IT'S SORT OF AN ERA OF AUSTERITY AND BELT CUTTING AND INCREASED SCRUTINY.

I HAVE COME IN PLEDGING TO REVIEW TOP TO BOTTOM ALL ASPECTS OF THE AGENCY AND ALL OF ITS FINANCIAL AND STRUCTURAL FACETS. AND HAVE, AS YOU MAY HAVE HEARD, ONE OF THE ISSUES THE GOVERNOR HAS BEEN VERY CONCERNED ABOUT ACROSS ALL OF HIS AGENCIES IS THE TRAVEL BUDGET. WE UNDERSTAND FROM HIM THAT HE'S REQUESTING ALL AGENCIES TO TAKE AT LEAST 50 PERCENT OUT OF THOSE BUDGETS AS A WAY OF CUTTING DOWN ON OVERHEAD. AND I, HEARING THAT, IMMEDIATELY SENT A MEMO TO ALL BOARD MEMBERS WHICH ANNOUNCED THAT THE OFFICE OF THE CHAIR IS GOING TO BE CUTTING BACK ON TRAVEL COSTS AT LEAST 50 PERCENT FOR THIS UPCOMING YEAR, 50 PERCENT FROM WHAT WE BUDGETED.

AND HAVE ASKED MICHAEL GOLDBERG TO TALK TO ALAN TO DISCUSS HOW THE REST OF THE AGENCY CAN COME IN LINE WITH THAT POLICY. SO THAT'S JUST THE FIRST OF A NUMBER OF WAYS THAT WE'RE GOING TO BE BELT TIGHTENING HERE AT THE AGENCY TO DO OUR PART AT THIS

TIME OF CONCERN FOR STATE GOVERNMENT IN GENERAL.

IN TERMS OF WHAT I HAVE BEEN DOING PERSONALLY, SPENT A LOT OF TIME FAMILIARIZING MYSELF WITH ALL ASPECTS OF THE AGENCY. REALLY GOT UP TO SPEED ON ALL OF THE WONDERFUL THINGS THAT HAVE TRANSPIRED OVER THE FIRST SIX AND A HALF YEARS SO AS TO SET THE STAGE FOR BEING ABLE TO DIRECT THE NEXT PHASE GOING FORWARD.

SPENT A LOT OF TIME WITH THE STAFF BOTH IN MY OFFICE AND WITH THE SCIENCE STAFF, A LOT OF TIME GETTING UP TO SPEED WITH THE PORTFOLIO OF ALL OF OUR PROJECTS WITH PROGRESS REPORTS ON HOW THOSE PROJECTS ARE GOING. SPENT A GREAT DEAL OF TIME WITH THE INDIVIDUAL BOARD MEMBERS TO LEARN MORE ABOUT WHAT IS IMPORTANT TO THEM AND WHAT ARE THE MAJOR ISSUES, CHALLENGES, AND OPPORTUNITIES AT THEIR REPRESENTATIVE INSTITUTIONS.

I HAD THE PLEASURE OF STARTING WHAT WILL BE A SERIES OF TOURS AROUND ALL OF OUR CONSTRUCTED FACILITIES THUS FAR, HAVING GONE TO USC, UCSF, AND YESTERDAY TO STANFORD'S FACILITY TO GET FULL TOURS TO HEAR ALL THE VERY EXCITING THINGS THAT ARE GOING ON THERE. I WILL SAY TO DR. PIZZO, WITH RESPECT TO STANFORD, THAT I COMMEND ANYBODY WHO'S NEVER HAD AN AIR SHOWER TO ENTER INTO AN AREA WHERE THEY WANT NO

CONTAMINATION. IT'S QUITE THE EXPERIENCE WHICH WE HAD YESTERDAY AND JUST A WONDERFUL TOUR.

I HAVE, IN ADDITION, IN THE COURSE OF THESE TOURS, AND THIS SORT OF GETS TO OUR CORE MISSION, MET WITH NUMEROUS OF THE INVESTIGATORS WHO ARE DOING THE FANTASTIC WORK THAT WE ARE FUNDING. AS WE'VE KNOWN FOR MANY YEARS, THESE PEOPLE WERE ADRIFT EARLIER IN THE DECADE BEFORE PROP 71 CAME ALONG AND ENABLED THEM TO GO OUT AND DO STEM CELL RESEARCH IN A COORDINATED AND COMPREHENSIVE WAY. THERE IS A TRUE PALPABLE SENSE OF EXTREME ENTHUSIASM AMONGST THESE SCIENTISTS AND A DECIDED MEASURE OF GRATITUDE TO CIRM FOR THE ROLE IT'S DOING IN ENABLING THEIR WORK.

SO IT WAS -- EVERY TIME YOU MEET WITH ANY OF THEM, YOU COME AWAY FEELING LIKE WE'RE DOING GREAT WORK HERE. AND I WANTED JUST TO UPDATE THE BOARD AND LET THEM KNOW THAT THE SENSE OF ENTHUSIASM NOT ONLY ISN'T DIMINISHING, BUT IS INCREASING AS THE PROJECTS GET FURTHER DOWN THE LINE.

WE TALKED ABOUT WHEN I WAS ELECTED A COUPLE OF MONTHS AGO I HAD A NUMBER OF PRIORITIES. I'VE SPENT A LOT OF TIME DEALING WITH THOSE. OBVIOUSLY FIRST AND FOREMOST WERE FINANCIAL MATTERS, MAKING SURE THAT CIRM'S FUNDING IS PRESERVED GOING

FORWARD AT THIS TIME, WHICH IS A TRICKY TIME AT STATE GOVERNMENT. I HAVE EXTENSIVELY BEEN DEALING WITH THE GOVERNOR AND TREASURER'S OFFICE TOWARDS DEVELOPING THE PLAN FOR CIRM'S FUNDING IN THE UPCOMING MONTHS AND HAVE BEEN VERY HAPPY WITH THE WAY THOSE DISCUSSIONS ARE GOING. THEY ARE WORKS IN PROGRESS AT THIS POINT. WE'LL BRING BACK TO YOU THE FULL DETAILS WHEN ALL IS SAID AND DONE.

INTERNALLY WE ARE GOING TO BE HAVING ON TODAY'S AGENDA A JOB DESCRIPTION FOR A CHIEF FINANCIAL OFFICER, WHICH WE ARE GOING TO BRING IN TO OVERSEE ALL OF THE INTERNAL AND EXTERNAL FINANCES OF THE ORGANIZATION. BE VERY HAPPY, IF WE APPROVE THAT DESCRIPTION AT THE BOARD MEETING TODAY, TO POST THAT JOB DESCRIPTION AND GET GOING ON FINDING THE RIGHT PERSON FOR THAT SLOT.

COMMUNICATIONS WE ALSO IDENTIFIED AS A MAJOR PRIORITY. WE'VE UNDERTAKEN A DE FACTO COMMUNICATIONS AUDIT OF WHAT WE'VE DONE IN THE PAST AND HAVE SET ABOUT DEVELOPING A STRATEGIC PLAN FOR COMPREHENSIVE AND ROBUST COMMUNICATIONS POLICY GOING FORWARD. WE ARE IN THE PROCESS RIGHT NOW OF IDENTIFYING CANDIDATES TO FILL THE POSITION OF DIRECTOR OF COMMUNICATIONS, WHO WILL OVERSEE THAT EFFORT AND WILL REPORT TO SENATOR TORRES AS CHAIR OF

THE COMMUNICATIONS SUBCOMMITTEE.

PART AND PARCEL OF ANY COMMUNICATIONS EFFORT ARE THE PATIENT ADVOCATES, WHO I'VE MADE IT A PRIORITY TO EXAMINE THEIR ROLE HERE AND TO EXPAND IT AS, AFTER ALL, THEY ARE OUR GREATEST SPOKESPEOPLE AND ARE RESPONSIBLE FOR THE VERY GOOD WILL THAT ALL OF THIS WORK ENGENDERS. BECAUSE THEY'RE VERY IMPORTANT AND BECAUSE ANY COMMUNICATIONS POLICY BY DEFINITION REQUIRES A LOT OF COORDINATION AND HELP FROM THE PATIENT ADVOCATES, THE ACTUAL POSITION THAT WE ARE CREATING AND LOOKING TO FILL IS, FULL TITLE IS GOING TO BE DIRECTOR OF COMMUNICATIONS AND PATIENT ADVOCATE OUTREACH. SO WE WILL BE APPROACHING ALL OF THIS IN A VERY COORDINATED FASHION.

WE'VE MADE A LOT OF STRIDES. THERE HAVE BEEN A LOT OF CONCERNS VOICED ABOUT HAVING SORT OF TWO SETS OF GOVERNANCE IN-HOUSE AT CIRM. ALAN AND I, I THINK, HAVE MADE GREAT PROGRESS IN SORT OF UNIFYING THE ENTIRE TEAM. WE HAVE STARTED UP AGAIN AN EXECUTIVE COMMITTEE WEEKLY MEETING WHERE MEMBERS OF THE SENIOR STAFF FROM BOTH THE OFFICE OF THE CHAIR AND THE PRESIDENT'S OFFICE MEET TO DISCUSS THE ISSUES OF THE DAY, WHICH I CAN ASSURE YOU THERE ARE NO SHORTAGE OF. WE HAVE YET TO FINISH EARLY ON ANY

OF THESE MEETINGS, BUT IT'S A GREAT WAY OF HAVING THOROUGH COMMUNICATION AND COOPERATION BETWEEN EVERYBODY IN THE OFFICE, WHICH I THINK IS A VERY HEALTHY THING. AND WE LOOK FORWARD TO MORE OF THE SAME.

FROM A STRUCTURAL POINT OF VIEW, WE HAVE NEW MEMBERS WHO ARE HERE. WE'VE GONE ABOUT IDENTIFYING SUBCOMMITTEES AT CIRM THAT THEY WOULD LIKE TO SERVE ON AND HAVE PLACED THEM WHERE THEY WOULD LIKE, WHICH HAS BEEN VERY HELPFUL. AND IT'S GREAT TO SEE THAT THEY ARE VERY ENTHUSIASTIC ABOUT THOSE PARTICULAR ROLES THAT THEY ARE ASSUMING.

ON THE THEME OF SUBCOMMITTEES, ANOTHER ONE OF THE MAJOR PRIORITIES THAT I HAD, WHICH WE'VE TALKED ABOUT, AGAIN, AT GREAT DETAIL, IS THE INCREASED INVOLVEMENT OF INDUSTRY IN THE CIRM PROGRAMS GOING FORWARD. BECAUSE THAT IS A MAJOR PRIORITY, WE'VE ELEVATED THAT, LIKEWISE, TO SUBCOMMITTEE STATUS. YOU WILL RECALL AT THE LAST BOARD MEETING CHAIRMAN KLEIN CREATED THE INTELLECTUAL PROPERTY SUBCOMMITTEE GIVEN THAT THERE ARE SO MANY ISSUES IN THAT FIELD THAT REQUIRE IMMEDIATE ATTENTION.

BECAUSE OF THE INTERTWINED NATURE OF INDUSTRY CONCERNS AND INTELLECTUAL PROPERTY

CONCERNS, WE HAVE JOINED THE TWO TOGETHER ON ONE SUBCOMMITTEE WHICH WILL NOW BE THE INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE, CO-CHAIRED BY STEPHEN JUELSGAARD AND DUANE ROTH. STEVE WILL BE THE CHAIR WITH RESPECT TO INTELLECTUAL PROPERTY MATTERS, DUANE WITH RESPECT TO INDUSTRY MATTERS. BOTH CHAIRS CHOSEN BECAUSE THEY HAVE EXTENSIVE AND LONG-STANDING EXPERIENCE WHICH IS INVALUABLE IN WHAT THEY BRING TO THE TABLE FOR THOSE COMMITTEES.

SO I THINK ON THE PERSONNEL FRONT, WE'LL GET TO THIS MORE LATER ON, BUT AS MANY OF YOU KNOW, OUR LONG-STANDING, TIRELESS, INVALUABLE COHORT MELISSA IS HEADED OFF TO STANFORD BUSINESS SCHOOL IN THE TWO SHORT COMING WEEKS. AND OBVIOUSLY THAT IS A CRITICAL POSITION. WE'LL HAVE MUCH MORE COMMENT ON MELISSA LATER, SO I DON'T WANT TO GET INTO THAT TOO MUCH NOW OTHER THAN TO SAY THAT AFTER AN EXTENSIVE SEARCH, WE HAVE IDENTIFIED HER SUCCESSOR, WHOM I'D LIKE TO INTRODUCE TO ALL OF YOU TODAY, WHICH IS MARIA BONNEVILLE. IF YOU COULD STAND AND SAY HELLO.

(APPLAUSE.)

CHAIRMAN THOMAS: MARIA STARTS NEXT WEEK, AND WE'RE DELIGHTED. AS I SAID TWO MONTHS AGO, IT'S AN IMPOSSIBLE TASK TO FOLLOW BOB. IT'S A SIMILARLY IMPOSSIBLE TASK TO FOLLOW MELISSA, BUT I AND MARIA

ARE GOING TO DO OUR BEST TO DO JUST THAT IN OUR EFFORT AS WE MARCH ON HERE TO THE NEXT PHASE OF CIRM BUSINESS.

SO THAT IS MY CHAIRMAN'S REPORT. I CAN REPORT TO YOU THAT I AM DELIGHTED TO BE HERE, TO BE WORKING WITH ALL OF YOU. WE'RE DOING WONDERFUL, WONDERFUL WORK. AND I COME TO WORK EVERY DAY JUST TOTALLY ENERGIZED AND LOOKING FORWARD TO WHAT WE CAN DO NEXT. SO I WANT TO THANK YOU AGAIN FOR THE OPPORTUNITY TO SERVE HERE.

WITH THAT, I WOULD LIKE TO TURN IT OVER TO PRESIDENT TROUNSON FOR THE PRESIDENT'S REPORT.

DR. TROUNSON: THANK YOU VERY MUCH, CHAIR. AND IT'S VERY NICE TO BE AGAIN AT THE FIRST MEETING THAT THE NEW CHAIR IS OVERSEEING. SO I HAVEN'T REALLY CHANGED THE FORMAT IN WHICH I'M GOING TO REPORT TO YOU BECAUSE I REALLY DO GET QUITE A LOT OF SUPPORT IN AT LEAST IDENTIFYING SEVERAL OF WHAT I THINK ARE THE KEY PAPERS THAT ARE COMING THROUGH.

ALSO WE DO THIS ON A MONTHLY BASIS. SO I HOPE YOU GET THE REPORTS THAT I SEND OUT TO EVERYBODY SO YOU GET A BIT OF AN INCREASED FLAVOR OF SOME MORE OF THE PAPERS THAT WE FIND.

IN THIS PARTICULAR PAPER, WHICH WAS ONE OF THE PAPERS OUT OF THE UCLA LAB OF ROBB MACLELLAN,

YOU WILL POSSIBLY RECALL THAT SOME AMPHIBIA AND TELEOST FISH CAN REGENERATE INJURED AND REMOVED HEART TISSUE. YOU CAN TAKE PART OF THE VENTRICLES OUT OF A FISH HEART, ZEBRAFISH HEART, AND THEY WILL REGENERATE THE REMAINDER OF THE HEART BACK TO THE ORIGINAL SIZE. IT'S THOUGHT THAT THAT'S HAPPENING REALLY BY DEDIFFERENTIATION AND PROLIFERATION.

WHY CAN'T THAT HAPPEN IN MAMMALS? WHY CAN'T WE REGENERATE PART OF OUR VENTRICLES THAT HAVE BEEN DAMAGED THROUGH HEART ATTACK? WELL, IT SEEMS THAT THE HEART MUSCLE EXITS THE CELL CYCLE. THE CELL CYCLE ALLOWS THE CELLS TO PROLIFERATE, TO MULTIPLY, BUT HEART MUSCLE EXITS THAT CELL CYCLE AND IS STABLY SILENCED BY THE E2F GENES THROUGH HETEROCHROMATIN. AND THIS SILENCES THE GENES, AND THIS HETEROCHROMATIN THAT IS RESPONSIBLE FOR THIS REALLY ACCUMULATES IN ANIMAL HEART TISSUE AS IT FORMS SO THAT YOU GET A LOCKDOWN ON THE ABILITY OF THOSE HEART MUSCLE CELLS TO PROLIFERATE. VERY FEW OF THEM CAN BE SHOWN TO MULTIPLY, VERY, VERY FEW. AND IT'S ARGUABLE WHETHER ANY OF THE HEART MUSCLE CELLS DO THAT. MAYBE THERE'S A SMALL POPULATION OF OTHER CELLS THAT WILL MULTIPLY LESS THAN 1 PERCENT OF THE HEART TISSUE OVER A LIFETIME.

SO IT'S A H3 CANINE TRIMETHYL-HISTONE

METHYLATION WHICH IS OBSERVED IN THE HETEROCHROMATIN, WHICH INCREASES IN THE HEART MUSCLE. AND THIS IS THIS REGULATED BY RETINOMA BLASTOMA GENES WITH THE E2F TRANSCRIPTION FACTORS RECRUITING HETEROCHROMATIN. AND IF THEY'RE KNOCKED OUT, IF THESE GENES ARE KNOCKED OUT, THE HETEROCHROMATIN IS REDUCED AROUND THE PROMOTERS OF THE CELL CYCLE RESUMPTION, AND YOU ACTUALLY GET HEART MUSCLE CELLS BEING RELEASED BACK INTO THE CELL CYCLE SO THEY CAN PROLIFERATE. THEREFORE, THE RB GENE, THE RETROBLASTOMA GENES AND THE P130 GENES HAVE A ROLE IN MAINTAINING POSTMITOTIC ARREST, KEEPING THE CELLS FROM MULTIPLYING BY SILENCING PROCESS.

AND IF YOU CAN RESTORE THE PROLIFERATIVE ABILITY OF CARDIOMYOCYTES BY TARGETING THESE GENES, IT MAY ENABLE A FISHLIKE REPAIR OF INJURED HEART TISSUE. SO WHAT I'M SHOWING YOU UP THERE, ON ONE SIDE THESE GENES WILL STABLY SILENCE THAT. AND IF YOU CAN ACTUALLY AFFECT THOSE GENES, YOU MAY ENABLE HEART MUSCLE CELLS TO COME BACK OUT AND PROLIFERATE. I THINK THAT'S A PRETTY IMPORTANT OBSERVATION BECAUSE IT MIGHT ALLOW US TO START TO FIGURE OUT WHAT WE COULD DO TO ENABLE SOME OF THOSE HEART MUSCLE CELLS TO START PROLIFERATING IN CASES OF

HEART DAMAGE. I THOUGHT IT WAS A VERY NICE PIECE OF WORK.

THE SECOND ONE, AND IT'S A PAPER OUT OF MICHA DRUKKER'S LAB HERE AT STANFORD. IT'S ANOTHER REALLY NICE PIECE OF WORK. WE'VE ALWAYS HAD THE PROBLEM WITH EMBRYONIC OR PLURIPOTENTIAL STEM CELLS THAT IF YOU GET ANY UNDIFFERENTIATED CELLS SURVIVING IN YOUR DIFFERENTIATION, THEY CAN GO ON AND PRODUCE A TERATOMA. SO IT'S A BIG ISSUE FOR THE REGULATORY AUTHORITY. IT'S A BIG ISSUE WHEN YOU COME TO TRANSPLANT PLURIPOTENTIAL STEM CELLS THAT HAVE BEEN DIFFERENTIATED IN WHATEVER CELL YOU LIKE. SO PARTICULARLY IN ALL THE EARLY DAYS OF TRANSPLANTATION, WE SAW A LOT OF TERATOMAS APPEARING BECAUSE THESE UNDIFFERENTIATED CELLS WERE STILL THERE, STILL THERE IN SUFFICIENT NUMBERS THAT THEY WOULD CAUSE THESE TERATOMAS.

WELL, MICHA DRUKKER'S GROUP HERE AT STANFORD IN THE STEM CELL CENTER, THEY RAISED A MONOCLONAL ANTIBODY AND THEY CALLED IT SSEA-5 THAT BINDS SPECIFICALLY TO AN H1-TYPE GLYCAN EXPRESSED SPECIFICALLY IN HUMAN PLURIPOTENTIAL STEM CELLS. THEY'VE ALSO GOT SOME OTHER MARKERS THAT ARE COMMON AND SPECIFIC TO THESE. AND SO WHEN YOU COMBINE THIS SSEA-5 ANTIBODY IN COMBINATION WITH TWO OF THE OTHER

MARKERS SHOWN IN THAT LINE, CD9, CD30, CD50, CD90, OR CD200, YOU ACTUALLY REMOVE, YOU IMMUNODEPLETE ALL THE INCOMPLETELY DIFFERENTIATED HUMAN EMBRYONIC STEM CELLS, AND NO TERATOMAS ARE FORMED, NONE.

NOW, I THINK THIS IS VERY NICE PIECE OF WORK. OTHER PEOPLE HAVE DESCRIBED METHODS FOR DOING THIS. THIS SEEMS A VERY COMPLETE STUDY. IT WAS PUBLISHED IN *NATURE BIOTECHNOLOGY*, AND I THINK IT'S A POWERFUL METHOD FOR REMOVING ANY TERATOMA-FORMING CELLS FOR RESEARCH OR CLINICAL APPLICATION. SO I THINK IT'S A GREAT PIECE OF WORK, AND IT'S ONE I THINK IS GOING TO BE UTILIZED VERY WIDELY.

THE OTHER PIECE OF WORK THAT I WANTED TO REFER TO YOU IS ANOTHER STUDY OUT OF THE JACOBSON LAB AT UCLA PUBLISHED IN *GENOME BIOLOGY*. YOU WILL BE AWARE THAT METHYLATION IS THE WAY THE GENOME HAS FOR SILENCING GENES. I'VE SPOKEN TO YOU BEFORE. IF YOU METHYLATE THE DNA, YOU WILL GENERALLY SILENCE THE GENES. SO YOU'VE GOT ISLAND, CPG ISLANDS THAT ARE SUBJECT TO METHYLATION, YOU WILL GET THOSE GENES IN THAT AREA SILENCED.

THERE'S ALWAYS BEEN AN INKLING THAT THERE IS THE OPPOSITE EFFECT, THE ROCKER EFFECT, AN ENHANCER SOMEWHERE. HOW DO YOU GET GENES TURNED ON? HOW DO YOU GET THEM EXPRESSED? SO IN

DIFFERENTIATION YOU WANT TO SILENCE, BUT YOU WANT TO GET SOME GENES TO BE EXPRESSED, TURN THEM ON. WELL, ACTUALLY NOW THEY HAVE FOUND IT BECAUSE THEY TOOK A GENOMEWIDE MAPPING OF THE 5HMC, WHICH IS A MOLECULE WHICH SORT OF OPERATES IN THE OPPOSITE DIRECTION.

SO IT'S FOUND IN GENES THAT ARE ACTIVE OR TURNED ON AND PRESENT ON ENHANCERS. THESE ARE THE ENHANCER SECTIONS OF THE GENES THAT ARE CRITICAL FOR MAINTAINING HUMAN EMBRYONIC STEM CELLS, EXAMPLE, OCT4 AND NANOG DNA BINDING SITES. SO NOW THEY'VE DISCOVERED THE OTHER COMPONENT TO THE SILENCING IS THE ACTIVATOR. NOW WE'VE GOT A VERY GOOD IDEA WHAT IS GOING TO TURN GENES ON AND OFF. AND STARTING TO UNDERSTAND THIS COMPLEX EPIGENOMIC REGULATORY SYSTEM IS VERY CRITICAL IN A WAY WE CAN ACTUALLY TURN GENES ON TO DO THE THINGS THAT WE ACTUALLY REALLY WANT THEM TO DO, TO TURN THEM INTO THE MATURE STATE, FUNCTIONAL STATE. SO I THINK IT'S, AGAIN, A VERY NICE PIECE OF WORK.

WELL, THEY WERE THREE OF THE PAPERS THAT ARE QUITE BASIC PAPERS, BUT I THINK VERY IMPORTANT PAPERS TO US. AND I THINK THEY'RE GOING TO UNDERPIN A LOT OF FURTHER WORK THAT'S GOING ON IN THE AREA. AND NOTICEABLY THOSE WERE OUT OF CALIFORNIA.

I THOUGHT I'D DRAW YOUR ATTENTION TO THE

INTELLECTUAL PROPERTY THAT'S EVOLVING OUT OF CIRM. I THOUGHT YOU SHOULD BE UPDATED ON IT. AS OF AUGUST 2011, THERE ARE 69 CIRM-FUNDED INVENTIONS THAT ARE REGISTERED WITH OUR GRANTS MANAGEMENT TEAM. THIRTY-TWO ARE SUBJECT TO PATENT FILING. SO THIS IS THE UPDATE AT THE MOMENT. IT MIGHT NOT SOUND LIKE A LOT OF PATENTS THAT ARE ACTUALLY FILED AT THE PRESENT TIME, BUT THIS IS AN EVOLVING PROCESS. IT TAKES TIME FOR THE INVENTIONS TO GO THROUGH THE PROCESS TO BE FILED.

SO GRANTEES ARE ACTIVELY SEEKING TO LICENSE THESE. TWO ARE OPTIONED TO SMALL COMPANIES TO DATE. THERE'S TWO OF THESE THAT HAVE GONE OFF TO UTILIZATION BY SMALL COMPANIES. SO THERE WILL BE AN UPDATE ON THE LICENSING NEXT MONTH, SO WE'LL EXPECT THIS TO CONTINUE TO LIFT AND PROBABLY ACCELERATE IN TIME. BUT GIVING YOU THE ACTUAL SITUATION ON INTELLECTUAL PROPERTY RIGHT OF NOW.

I WAS ALSO ASKED BY THE EXECUTIVE TO GIVE YOU A QUICK UPDATE ON THE ALLIANCE FOR REGENERATIVE MEDICINE. AND I THINK THAT WAS INCLUDED IN YOUR PAPERS. AND SO PLEASE READ IT AT YOUR LEISURE. THIS IS THE ORGANIZATION THAT REPRESENTS BROADLY ALL OF THE COMPANIES IN THE STEM CELL SPACE, BUT ALSO ORGANIZATIONS AS WELL, BUT PRINCIPALLY COMPANIES AND

ORGANIZATIONS AND INCLUDES SOME UNIVERSITY ORGANIZATIONS, BUT NOT SO MANY OF THE NOT-FOR-PROFIT, BUT IT'S GOT ALMOST ALL OF THE STEM CELL COMPANIES IN THE U.S. INVOLVED. AND THEY'RE NOW WIDENING THAT TO AN INTERNATIONAL BASIS.

SO THERE'S A GOVERNMENT RELATIONS COMMITTEE. THEY HAVE BEEN ABLE TO GET 11 BIPARTISAN SUPPORTERS FOR THE REGENERATIVE MEDICINE PROMOTION ACT 2011 IN THE HOUSE AND CONGRESSIONAL SUPPORT FOR NIST FOR REGENERATIVE MEDICINE ACTIVITIES. THAT'S NATIONAL INSTITUTES FOR STANDARDS. THAT'S PRETTY IMPORTANT TO GET BECAUSE IF THEY'RE INSTRUCTED TO ASSIST IN THIS WAY, THEY CAN HELP US ALL DEVELOP STANDARDS THAT ARE NECESSARY FOR THE REGULATORY PROCESSES IN THE REGISTRATION OF CLINICAL TRIALS, FOR EXAMPLE.

THE HOUSE APPROPRIATIONS SUBCOMMITTEE ON COMMERCE, JUSTICE, AND SCIENCE IS NOW SUPPORTING FOR REGENERATIVE MEDICINE IN 2012, WHICH IS GOOD. ARM'S GIVING BRIEFING TO U.S. HOUSE TRICAUCUS, AND THEY'VE DONE THAT BRIEFING, AND THEY'LL ALSO BRIEF THE SENATE IN THE FALL. SO THERE'S A LOT OF ACTIVITY DOWN THERE AT THE GOVERNMENT LEVEL.

THERE'S A REGULATORY AND REIMBURSEMENT COMMITTEE, AND THAT'S IMPORTANT FOR US TO KEEP

ABREAST OF. THEY'RE HAVING REGULAR MEETINGS ARRANGED WITH THE FDA FOR ISSUES OF MUTUAL CONCERN. AND THE INDUSTRY, ARM, THAT IS, THEY'RE ABLE TO NOMINATE A NONVOTING REPRESENTATIVE TO SERVE ON THE CELL, TISSUE, AND GENE THERAPY ADVISORY COMMITTEE. AGAIN, HAVE SOMEBODY INTERNAL THERE TO REPRESENT VIEWS FROM THE INDUSTRY IN PARTICULAR.

THERE'S A SCIENCE AND TECHNOLOGY COMMITTEE FOR WHICH I CHAIR, AND IT'S ESTABLISHED A PROJECT ON CELL POTENCY ASSAYS FOR REGULATORY GUIDANCE. CELL POTENCY IS ONE OF THE REALLY DIFFICULT AREAS TO GET ASSAYS AND TO GET AGREEMENT BECAUSE THERE'S SUCH A DIVERSITY OF CELLS AND THEIR ORIGINS.

SO THERE'S FOUR WORKING GROUPS ESTABLISHED, ONE ON METHODS REGISTRY. AND THAT IS BEING CO-CHAIRED BY ELLEN FEIGAL HERE WITH SOME SUPPORT FROM US. A SECOND WORKING GROUP ON REFERENCE METHODS AND MATERIALS, A THIRD ONE ON ASSAY DEVELOPMENT AND VALIDATION, A FOURTH ONE ON ANALYTICAL TECHNOLOGY.

WE EXPECT THESE WORKING GROUPS TO REPORT OVER THE NEXT SIX TO 12 MONTHS, AND THIS WILL DIRECTLY HELP US. THIS IS A WAY IN WHICH IT WILL REACH OUR CAPACITY TO ASSIST INDUSTRY AND OUR ACADEMIC COLLEAGUES IN MAKING THEIR WAY THROUGH THE

REGULATORY PROCESS. IT'S A VERY IMPORTANT PROCESS THAT'S GOING ON, AND IT'S TAKING A LOT OF PEOPLE'S TIME, INCLUDING, AS I SAID, ELLEN FEIGAL AND ONE OF OUR OTHER SCIENCE OFFICERS WHO ARE INVOLVED IN THIS.

THERE'S A SCIENCE AND TECHNOLOGY -- I'VE SAID THAT. THERE'S A MEMBERSHIP COMMITTEE. THERE ARE 81 ORGANIZATIONS AND COMPANIES INVOLVED IN THAT. THERE'S A COMMUNICATIONS SUBCOMMITTEE WITH AN ACTIVE AWARENESS PROGRAM IN MAINSTREAM MEDIA. AS PART OF THEIR ACTIVITIES, THERE'S A STEM CELL MEETING ON THE MESA CONFERENCE ON NOVEMBER THE 29TH. IT'S BEING COHOSTED BY CIRM, AND PARTICULARLY THE INVOLVEMENT OF ELONA BAUM. IT'S THE FIRST INVESTIGATOR AND PARTNERING FORUM FOR STEM CELL AND REGENERATIVE MEDICINE COMPANIES. AND I THINK, ELONA, THERE ARE SIX, WE'RE HOPING THAT SIX OF OUR TEAMS WILL PARTICIPATE IN THAT. AND I THINK THERE'S 32 SPOTS. SIX OF THOSE SPOTS ARE FROM ACTIVITIES THAT ARE GENERATING FROM CIRM. SO IT WILL BE VERY INTERESTING TO SEE HOW THAT GOES.

DUANE ROTH IS VERY MUCH INVOLVED WITH THAT PARTICULAR MEETING ON THE MESA. AND SO IT'S A GOOD ONE TO ATTEND. IT'S A VERY INTERESTING CONFERENCE, THAT ONE, AND PARTICULARLY RELEVANT TO WHAT OUR INTERESTS ARE.

THERE ARE A NUMBER OF NEW APPOINTMENTS. GLAD TO SEE THE NEW APPOINTMENT IN THE CHAIR'S OFFICE. THAT'S TERRIFIC. BUT IN THE OFFICE OF THE MANAGER, OFFICE MANAGER AT CIRM, PAUL FRECH HAS BEEN APPOINTED. WENDY ROGERS IS APPOINTED AS GRANTS MANAGEMENT SPECIALIST. CELESTE HEIDLER IS REPLACING, IF YOU CAN EVER REPLACE, MARGARET. WE HAD SEVERAL FAREWELLS FOR MARGARET AND FROM THE FINANCE OFFICE. AND SHE'S BEEN A WONDERFUL CONTRIBUTOR TO OUR ORGANIZATION AND IS A REAL BOND THROUGHOUT THE ORGANIZATION. BUT WE'RE ESPECIALLY PLEASED TO HAVE CELESTE JOIN US, WHO'S HAD A VERY LONG CAREER IN PUBLIC SERVICE. I WONDER IF YOU'D SORT OF STAND UP.

(APPLAUSE.)

DR. TROUNSON: WE ALSO APPOINTED NATALIE DEWITT, THE SPECIAL PROJECTS OFFICER TO THE PRESIDENT. SHE WAS IN THE PAST AN EDITOR FOR *NATURE*, AND SHE'S ALSO BEEN MORE RECENTLY HEAD OF SCIENCE AFFAIRS FOR THE PASTEUR INSTITUTE. SO SHE'S ARRIVING IN SEPTEMBER.

AND LISA KADYK, I HOPE I'VE GOT THE PRONUNCIATION RIGHT, AS A NEW SCIENCE OFFICER WHO'S APPOINTED INTO THE SCIENCE OFFICE.

UPCOMING RFA'S, JUST TO REMIND YOU. THE

DISEASE TEAM THERAPY DEVELOPMENT, THE PLANNING APPLICATIONS ARE GOING TO BE ASSESSED AT THIS BOARD MEETING, AND THE FUNDING PERIOD BEGINS SEPTEMBER THE 1ST. THE PART 2 RESEARCH AWARD WILL BE POSTED IN SEPTEMBER, AND SO THAT'S VERY CLOSE NEARBY FOR THE MAIN PART OF THAT RFA.

EARLY TRANSLATIONAL III PROGRAM, RFA POSTING ON JUNE THE 13TH, GRANTS WORKING GROUP REVIEW OF APPLICATIONS IS EXPECTED IN MARCH 2012.

AND THE CIRM STEM CELL BIOLOGY IV, THE BASIC PROGRAM CONCEPT PROPOSAL WILL COME TO THE BOARD IN OCTOBER THIS YEAR.

THERE WAS A CIRM 2011 BRIDGES TO STEM CELL ANNUAL RESEARCH TRAINEE MEETING IN SAN FRANCISCO ON JULY 7TH THROUGH THE 8TH THAT ATTRACTED 195 PARTICIPANTS, INCLUDING PROGRAM DIRECTORS, MENTORS, ICOC MEMBERS, CIRM STAFF, AND 130 TRAINEES. THERE WERE TALKS BY LEADERS IN STEM CELL RESEARCH IN CALIFORNIA, INCLUDING JANE LEBKOWSKI, CATRIONA JAMIESON, JENNIFER MANILAY, MAURICIO ROJAS, BERT LUBIN FROM THE BOARD, FRED GAGE, MAHENDRA RAO, RENEE REYO PERA, AND RON EVANS. AND THERE WAS ALSO A CAREER PANEL THAT WAS CHAIRED BY FRANCISCO PRIETO, JENNIFER MANALAY, IRENE GRISWALD PENA, ELLEN FEIGAL, AND MICHAEL YAFFE. THERE WERE 105 POSTER

PRESENTATIONS BY THE BRIDGES TRAINEES. AND I THINK WE HAVE UP ON OUR WEBSITE A VIDEO ON THAT PROGRAM.

IT'S A VERY, VERY SUCCESSFUL MEETING. PEOPLE WERE DELIGHTED TO BE THERE. THEY HAD A CHANCE TO GET ONE ON ONE WITH SOME OF THE RESEARCH LEADERS IN STEM CELLS. AND REALLY THEIR ENTHUSIASM IS ABSOLUTELY OVERWHELMING.

THE CREATIVITY AWARDS PROGRAM HAD A SUMMER THIS YEAR PILOT PROGRAM THAT INVOLVED UCSF, UNIVERSITY OF CALIFORNIA SANTA BARBARA, STANFORD, AND UNIVERSITY OF CALIFORNIA DAVIS. IT HAD FOUR TO SIX JUNIOR/SENIOR SCIENTISTS PER PROGRAM FROM THE CALIFORNIA HIGH SCHOOLS, A TOTAL OF 22 STUDENTS. STUDENTS ACCEPTED IN THE PROGRAMS WERE BASED ON ACADEMIC ACHIEVEMENT AND SOCIOECONOMIC STATUS.

IN THE PROGRAM ACTIVITIES, THEY HAD RESEARCH AND TRAINING ACTIVITIES AND MENTORING IN THE PI'S LAB, WEEKLY LECTURES, DISCUSSIONS, AND MEETINGS. THERE WERE 18 POSTERS PRESENTED AT CIRM, A SPONSORED POSTER DAY WHICH IS HELD AT CHORI THANKS TO BERT LUBIN IN OAKLAND IN AUGUST ON AUGUST THE 2D. AND FOUR STUDENTS WERE RECOGNIZED FOR VERY HIGH ACHIEVEMENTS AND WERE INVITED TO GIVE A TEN-MINUTE PRESENTATION ON THEIR SUMMER RESEARCH.

I WAS REALLY KNOCKED BACK BY THESE

STUDENTS. ACTUALLY WHEN I FIRST MET THEM WHEN I WAS AT DAVIS, I THOUGHT THEY WERE POST DOCS. THEY WERE INCREDIBLY SMART PEOPLE. AND IF THEY'RE IN THIS -- THE CREATIVITY PROGRAM REQUIRES THAT THEY NOT ONLY DO STEM CELLS, BUT THEY DO MUSIC, ACTING, ONE OTHER SOMETHING, PHYSICS, SOMETHING WHICH IS RIGHT OUT OF THE FIELD. AND WHAT THEY BRING WITH THAT CREATIVE ELEMENT WHERE THERE'S A DUALITY IS ASTONISHING. IT WAS JUST FANTASTIC. AND I ACTUALLY THINK THIS IS A WONDERFUL PROGRAM, AND I'D LIKE YOU TO MEET THOSE STUDENTS SOMETIME. YOUNG PEOPLE FINISHING HIGH SCHOOL, WOW. THIS STATE'S GOT SOME TALENT, I TELL YOU. IF THAT'S A SAMPLING OF THE TALENT, IT'S JUST EXTRAORDINARY AND WONDERFUL.

HOPEFULLY THEY WILL BE ATTRACTED TO CONTRIBUTE TO THE REGENERATIVE MEDICINE FIELD, BUT WHATEVER, THEY CERTAINLY KNOW ABOUT IT NOW.

THERE'S A WORKSHOP THAT WAS HELD IN FRANCE, THE AGENCE NATIONALE DE LA RECHERCHE HELD IN JULY IN PARIS, ATTENDED BY NINE CALIFORNIA SCIENTISTS AND 11 FRENCH SCIENTISTS, A MIXTURE OF THE TWO SETS OF SCIENTISTS TO SEE WHETHER WE COULD ENCOURAGE SOME COLLABORATIVE RESEARCH PROGRAMS. IT INVOLVED UCSF, UCLA, UC IRVINE, UNIVERSITY OF CALIFORNIA AT SANTA BARBARA AND SAN DIEGO, STANFORD,

AND ROCHE, AND THE PASTEUR INSTITUTE, I-STEM, IGBMC, IBENS, ET AL.

THE FOCUS WAS ON BASIC BIOLOGY BECAUSE THE FRENCH WERE INTERESTED MORE IN THE BASIC SCIENCE AND HOW TO MAKE CONNECTIONS THERE. THEIR ACTIVITIES INVOLVED SCIENTIFIC PRESENTATIONS AND POLICY DISCUSSIONS, NETWORKING, COLLABORATIVE BUILDING STRATEGIES. SO WE WOULD EXPECT NOW THE FRENCH TO ENGAGE WITH US, AND I WOULD EXPECT IN THE FUTURE SOME COLLABORATIVE RESEARCH GRANTS COMING PROBABLY INITIALLY THROUGH THE BASIC SCIENCE INVOLVING FRENCH AND CALIFORNIAN SCIENTISTS. THERE'S SOME WONDERFUL SCIENCE BEING DONE IN FRANCE. THERE'S SOME FANTASTIC WORK, AND IF THAT'S LINKED TOGETHER WITH SOME OF THE INITIATIVES IN CALIFORNIA, AGAIN, WE'LL GET TERRIFIC LIFT THERE.

WE'VE HAD A NUMBER OF DISCUSSIONS AT OUR EXECUTIVE BOARD, AS THE CHAIR TOLD YOU, ABOUT THE UPCOMING INSTITUTE OF MEDICINE REVIEW AND THE FACT THAT WE HAD TO PREPARE A STRATEGIC PLAN REVISION IN 2012. THE VIEW OF THE BOARD, THE EXECUTIVE, WAS THAT IT WOULD BE CRAZY TO HAVE THAT STRATEGIC PLAN HAPPEN AFTER THE REVIEW, AND THAT WE SHOULD PUT IT ON A FAST TRACK TO GET A REVISION OF THE STRATEGIC PLAN AVAILABLE SO THAT THE INSTITUTE OF MEDICINE

COULD CONSIDER IT, BEING THE UP-TO-DATE VIEW OF THE DIRECTION THAT THE INSTITUTE IS TAKING.

IT IS A STRATEGIC PLAN. IT'S A LIVING PLAN WITH SOME SET TIMES FOR OUTSIDE REVIEW. AFTER YEAR THREE, A 2009 REVISION TO THE STRATEGIC PLAN, 2010 EXTERNAL ADVISORY PANEL, THAT WAS A REQUIREMENT, AND 2012 WE'RE REQUIRED TO REVISE THE PLAN REFERENCING THE 2011 RESPONSE TO THE EXTERNAL ADVISORY PANEL'S RECOMMENDATION.

SO WE'VE STARTED BY CREATING A PROPOSED TIMELINE. SO I'M BRINGING THIS TO YOU TO GET SOME INPUTS FROM YOU, GET YOU AWARE THAT THIS IS GOING TO HAPPEN.

WE'VE HAD AN ALL-DAY RETREAT BY SENIOR STAFF ON AUGUST THE 18TH TO START THINKING ABOUT THIS WITH SOME PROFESSIONAL ASSISTANCE. AND ON AUGUST 25TH I'M TELLING YOU ABOUT THE INPUT ON THE PROPOSED PROCESS, SEEKING TO HAVE SOME GUIDANCE FROM YOU ON THE PROCESS.

IN SEPTEMBER THE 12TH WE WOULD HOPE TO DEVELOP SOME SORT OF DRAFT OF STRATEGIC ADJUSTMENTS FOR CONSIDERATION AND ADDED OR REVISED GOALS FROM OUR 2009 REVISION. AND SEPTEMBER 13TH THERE'S A MEETING WITH THE CALIFORNIA STEM CELL RESEARCH DIRECTORS AND NATIONAL LEADERS HELD IN CONJUNCTION

WITH CIRM. SO WE'RE GOING TO TAKE THAT OPPORTUNITY TO TALK TOGETHER WITH THEM ABOUT OUR STRATEGIC DIRECTION, BRINGING IT TO THE ICOC BOARD IN OCTOBER, THE FIRST OPPORTUNITY. SO THE CHAIR HAS RECOMMENDED THAT WE TAKE SOME TIME AT THE OCTOBER BOARD TO LOOK AT A DRAFT OR SUGGESTED REVISIONS AND HAVE THE ICOC'S INPUT INTO IT.

WE'RE PROPOSING SEPTEMBER THROUGH TO NOVEMBER TWO PUBLIC MEETINGS, ONE IN NORTHERN CALIFORNIA AND ONE IN SOUTHERN CALIFORNIA, WITH THE SPECIAL INVITES TO ALL GRANTEES AND PATIENT ADVOCATES. TWO INDUSTRY MEETINGS AGAIN IN NORTHERN AND IN SOUTHERN CALIFORNIA WITH INVITATIONS TO BIOTECH AND PHARMA TO PARTICIPATE.

CONFERENCE CALL WITH CLINICAL DEVELOPMENT ADVISORS, CALLS TO LEADERS OF PROFESSIONAL TRADE ALLIANCES, FOR EXAMPLE, THE ISSCR, THE INTERNATIONAL SOCIETY FOR TRANSPLANTATION, AND THE ARM ORGANIZATION TO GET THEIR VIEWS. CONFERENCE CALL WITH OUR COLLABORATIVE FUNDING PARTNERS. GET AS MANY OF THE INPUTS AS WE CAN.

AND NOVEMBER THE 7TH TO DECEMBER THE 1ST GET ANOTHER RETREAT TO DEFINE THE ADJUSTMENTS UNDER CONSIDERATION AND ADDED GOALS AND GET SOME SORT OF REVISION TO SENIOR MANAGEMENT BY DECEMBER THE 1ST.

GET TO THE JANUARY MEETING FOR THE THIRD REVISION TO THE ICOC BOARD FOR INPUT. HAVE FEBRUARY THE 15TH ICOC BOARD COMMENTS BACK TO SENIOR STAFF, AND HOPEFULLY BY MARCH THE 1ST THE FINAL VERSION READY FOR ICOC CONSIDERATION AND VOTE. SO THAT'S WHAT WE'VE PROPOSED. THAT'S WHAT WE'VE TALKED WITH OUR EXECUTIVE ABOUT. SO WE WOULD WELCOME ANY INPUTS ON THAT.

THERE'S A CIRM 2011 GRANTEE MEETING IN SAN FRANCISCO ON SEPTEMBER THE 14TH THROUGH THE 16TH, JUST TO REMIND YOU, TO BRING TOGETHER INVESTIGATORS AND TRAINEES FUNDED BY CIRM AND CIRM'S COLLABORATIVE FUNDING PARTNERS. IT'S TO HIGHLIGHT GRANTEE WORK FROM BASIC THROUGH TO TRANSLATION OF CLINICAL RESEARCH, ENCOURAGING SCIENTIFIC EXCHANGE AND COLLABORATION. IT'S THE BEST MEETING, SAID TO BE THE BEST MEETING IN STEM CELLS IN THE WORLD. THIS IS WHAT THE PEOPLE SAY THAT ATTEND IT.

SO ON THE AGENDA THERE'S PLENARY TALKS BY CIRM PRINCIPAL INVESTIGATORS AND OTHER LEADERS OUTSIDE CALIFORNIA IN THE FIELD. SO THEY'RE REALLY TERRIFIC TALKS. POSTERS AND SHORT TALKS BY TRAINEES. NETWORKING OPPORTUNITIES AND TRAINING OPPORTUNITIES AND PUBLIC COMMUNICATION AND ADVOCACY. SO IT'S A GREAT MEETING. WE'RE GOING TO HAVE SOME

OF THE BUSINESS GROUPS REPRESENTED ALSO IN PART OF THIS MEETING TO GET THEM TO DEMONSTRATE SOME OF THEIR WARES, SOME OF THEIR OPPORTUNITIES FOR THE CALIFORNIA GRANTEES AS WELL.

I THINK IT'S A GREAT MEETING. I THINK I'VE ENJOYED EVERY MOMENT OF THOSE MEETINGS. THEY'RE JUST SO INSPIRING. WE HOLD THEM UNDER COLD SPRING HARBOR RULES SO THAT THE ABSOLUTE DATA RIGHT UP TO DATE IS BEING GIVEN. WE DON'T REPORT ANY OF THE INFORMATION. BUT IF THE PRESENTERS OR THE AUTHORS WANT TO TALK TO PRESS, THAT'S THEIR BUSINESS, BUT WE DON'T. SO IT'S COLD SPRING HARBOR RULES. AND THAT REALLY GIVES EVERYBODY A CHANCE TO TALK TO THE SCIENTISTS ABOUT WHAT'S ACTUALLY RIGHT ON THE PACE RIGHT THERE AND THEN.

THERE'S A GRANTS MANAGEMENT REVISION DEVELOPMENT. CAN I ASK PAT OLSON TO PRESENT THIS TO YOU? WE WERE ASKED TO DO THAT.

DR. OLSON: I'M JUST FOLLOWING UP ON A REQUEST THAT WAS MADE EARLIER TO GIVE A BIT OF AN UPDATE ON WHAT WE'RE DOING IN OUR I.T. GROUP. AND SO THERE WAS A HANDOUT THAT IS PART OF THE PRESIDENT'S REPORT AND I THINK BEHIND TAB 5 THAT GOES INTO A LITTLE BIT MORE DEPTH. BUT I BASICALLY JUST WANTED TO HIGHLIGHT TO YOU THAT ESSENTIALLY

WHAT WE'RE REALLY TRYING TO DO IS WE'RE CONTINUING TO MOVE TO ONLINE FUNCTIONALITY FROM PDF.

SO RECENTLY WE'RE DOING MORE COMPLEX, WE'RE ADDING MORE COMPLEX ELEMENTS TO OUR PREAPPLICATION FOR OUR APPLICATIONS. THE BIG DEAL NOW IS WE'RE STRIVING TO GET BOTH THE EARLY TRANSLATION III AND THE DISEASE TEAM THERAPY DEVELOPMENT APPLICATION TO BE OUT BY THE END OF OCTOBER. AND THIS IS GOING TO INTRODUCE ONLINE BUDGET FUNCTIONALITY, WHICH WE HAVEN'T HAD TO DATE. SO WE'VE BEEN KEEPING OUR PROGRAMMERS BUSY FOR THAT.

ANOTHER THING IS OUR PREFUNDING ADMINISTRATIVE REVIEW. THAT'S ALWAYS BEEN A PDF-BASED PROCESS. AND NOW WE'RE WORKING TO GET THAT TO BE AN ONLINE PROCESS. AND THAT FOLLOWS ON FROM -- I THINK WE'VE TOLD YOU BEFORE ABOUT WE'RE DOING ANNUAL ONLINE PROGRESS REPORTING NOW. OUR GRANTEES CAN GO ONLINE TO DO THAT. ALSO PUBLICATION REPORTING IS CURRENTLY ONLINE.

SO WHAT WITH PUTTING THE PFAR PROCESS, THE PREFUNDING ADMINISTRATION REVIEW, TRYING TO GET OUR INVENTION DISCLOSURE PROCESS ONLINE, THESE ARE GOING TO BE NEXT STEPS.

ANOTHER THING THAT IS NOT UP HERE, BUT IS ACTUALLY IMPORTANT FOR BEING EFFICIENT WITH THE USE

OF DEVELOPER TIME IS OUR DEVELOPERS HAVE DEVELOPED WHAT I'LL CALL SOME SELF-SERVICE ADMINISTRATIVE SCREENS. SO SOMEONE WHO IS NOT A DEVELOPER CAN ADDRESS ISSUES THAT ARISE FROM GRANTEES OR FROM PEOPLE WHO HAVE QUESTIONS. SO WE'VE DONE THAT.

ANOTHER IMPORTANT PART OF WHAT WE'RE DOING IS PUBLIC WEBSITE INTEGRATION. SO WHAT WE HAVE DONE, OUR DEVELOPERS HAVE COMPLETED THE DATA PIPELINE BETWEEN THE GRANTS PORTAL AND THE PUBLIC WEBSITE. WHAT THAT MEANS IS THAT WILL ENABLE TRANSMITTAL TO THE PUBLIC WEBSITE OF INFORMATION SUCH AS PUBLIC ABSTRACTS FROM PROGRESS REPORTS, PUBLICATION DISCLOSURES. AND WHAT WE'RE AWAITING NOW IS THERE'S A THIRD-PARTY VENDOR WHO'S ACTUALLY RESPONSIBLE FOR MAKING THE PUBLIC WEBSITE BE ABLE TO USE THAT DATASET. SO WE'RE PLEASED THAT THAT SHOULD HOPEFULLY COME ONLINE PRETTY SOON.

PROBABLY MOST IMPORTANTLY OR VERY IMPORTANT, I THINK, IS THAT WE HAD OUR FIRST EVER EXTERNAL SECURITY AUDIT OF THE CIRM NETWORK. SO I THINK YOU ALL HAVE HEARD OF HACKING INTO E-MAIL SYSTEMS AND INTRODUCTION OF VIRUSES AND THINGS LIKE THAT. WE HIRED AN AGENCY TO ESSENTIALLY PRESSURE TEST OUR NETWORK. AND THIS WAS RECENTLY COMPLETED, AND THE REPORT GAVE US AN ABOVE AVERAGE OVERALL

RATING. SO WE'RE ACTUALLY VERY PROUD OF THAT.

THE NEXT PHASE IS THAT SAME GROUP IS GOING TO TRY AND PRESSURE TEST OUR OTHER TWO EXTERNALLY ACCESSIBLE SYSTEMS, WHICH IS THE GRANTS MANAGEMENT SYSTEM. OBVIOUSLY IF YOU'RE SETTING UP ONLINE ACCESS FOR GRANTEES TO GET IN AND REPORT AND SUCH, THAT MEANS ARGUABLY OTHERS COULD GET IN AS WELL. SO THAT'S ONE OF THE THINGS THEY'RE GOING TO TEST AS WELL AS THE PUBLIC WEBSITE TO SEE IN. THAT'S THE NEXT PHASE.

FINALLY, WE HAVE DONE SOME INFRASTRUCTURE --

DR. PIZZO: COULD YOU JUST GIVE US A LITTLE MORE CONTEXT ON THE EXTERNAL REVIEW AND PRESSURE TESTING? I'M NOT SURE WHAT ABOVE AVERAGE MEANS.

DR. OLSON: SO WHAT THEY DO IS ASSESS, THEY LOOK AT A NUMBER OF DIFFERENT PARAMETERS. AND YOU'RE NOT TALKING TO AN I.T. EXPERT HERE. SO I WILL GIVE YOU THE -- THEY LOOK AT A NUMBER OF DIFFERENT PARAMETERS, AND THEY SCORE THEM AS TO WHETHER THEY HAVE CRITICAL ISSUES ASSOCIATED WITH THEM, HIGH CONSIDERATION, OF MEDIUM CONSIDERATION, OF LOW, OR FOR YOUR INFORMATION. ANYTHING THAT HAS A RATING -- ANYTHING THAT THEY FIND THAT THEY

CONSIDER MEDIUM OR HIGHER REQUIRES ATTENTION.

WE HAD TWO IN THE MEDIUM CATEGORY, WE HAD TWO IN THE LOW CATEGORY, AND TWO IN THE INFO CATEGORY. WE HAD NOTHING IN THE HIGH OR CRITICAL ISSUES. SO COMPARED TO OTHER ORGANIZATIONS AND TO STANDARDS SET, WE SCORE OVERALL ABOVE AVERAGE. SO I HOPE THAT HELPS A LITTLE BIT.

THE OTHER THING THAT WE HAVE DONE IS INFRASTRUCTURE UPGRADES. AND THIS IS BASICALLY TO ENSURE RELIABILITY OF ACCESS AND DATA INTEGRITY SHOULD WE HAVE SOME -- WELL, SHOULD THERE BE DISASTER RECOVERY. IF A SERVER SHOULD FAIL, IS THERE A BACKUP AUTOMATIC SWITCH? SO THAT WAS REALLY ALL TO UPGRADE THAT.

SO IF THERE AREN'T ANY QUESTIONS, THAT'S ALL I HAVE TO SAY ABOUT THAT. THANK YOU.

DR. TROUNSON: SO THIS IS A CURRENT PICTURE OF ALL OUR WONDERFUL PEOPLE IN THE MANAGEMENT TEAMS AT CIRM. AND IF I CAN ASK CHILA IF SHE WILL JUST PRESENT YOU THE BRIEF OF THE 2010-11 BUDGET ALLOCATION AND EXPENDITURE REPORT.

MS. SILVA-MARTIN: GOOD MORNING, MR. CHAIR AND MEMBERS OF THE BOARD. I'M JUST GOING TO GIVE YOU A BRIEF UPDATE ON OUR '10-'11 BUDGET SINCE IT'S BEEN SOME TIME SINCE WE PROVIDED A REPORT.

I FIRST WANT TO POINT OUT THAT OUR FINANCIAL BUDGET IS DONE ON A JULY 1ST THROUGH JUNE 30TH BASIS. AND I AM REPORTING ON EXPENDITURES THROUGH JUNE 30TH, SO FOR THE FISCAL YEAR. BUT I WANT TO POINT OUT THAT OUR FINANCIAL REPORT THIS TIME IS BASED ON WHAT THOSE OF US IN STATE GOVERNMENT CALL MONTH 12. SO WHAT HAPPENS DURING THE YEAR-END PROCESS FOR STATE GOVERNMENT IS WE ACTUALLY RUN TWO SETS OF REPORTS. WE CLOSE OFF THE BOOKS AS OF JUNE 30TH. SO EVERYTHING THAT'S RECORDED, WE CLOSE OFF THE BOOKS AT THAT TIME, AND WE RUN A SET OF FINANCIAL STATEMENTS. AND THEN WE HAVE -- WHAT WE DO IS A FINAL YEAR-END STATEMENT WHICH WILL INCLUDE ALL THE LAGS AND ACCRUALS FOR THE YEAR-END. SO THIS REPORT DOES NOT INCLUDE THE LAGS AND ACCRUALS. SO IT'S NOT THE FINAL STATEMENT.

SO IN GOING OVER THE NUMBERS, BEFORE I ACTUALLY DO THAT, I WANTED TO POINT OUT THAT THERE ARE THREE SETS OF BARS. FOR EACH OF THE BARS, THE BLUE BAR, FOR EACH GROUP THE BLUE BAR REPRESENTS THE ACTUAL ALLOCATION THAT WAS APPROVED FOR OUR BUDGET. THE ORANGE BAR, THE SECOND BAR, WILL REPRESENT WHAT WE'VE ACTUALLY POSTED OR RECORDED ON OUR FINANCIAL STATEMENTS AS OF MONTH 12, JUNE 30TH. AND THEN THE GREEN REPRESENTS WHAT OUR BALANCE IS.

SO IN LOOKING OVER THE FIRST SET OF BARS, WE WERE ALLOCATED A TOTAL OF $8,848,000. AS OF JUNE 30TH, WE RECORDED EXPENDITURES OF $8,137,000, LEAVING A BALANCE OF 710,000. NOW, THIS REPRESENTS ABOUT 92 PERCENT OF OUR BUDGET ALLOCATION WAS ACTUALLY SPENT. IN THIS CATEGORY WE DON'T REALLY EXPECT MANY ACCRUALS OR LAGS BECAUSE THE EXPENDITURES ARE PRETTY ACCURATE IN THIS CATEGORY.

WHERE WE'LL SEE A BIG DIFFERENCE FROM MONTH 12 TO OUR FINAL YEAR-END STATEMENTS IS IN OUR OPERATING EXPENDITURES, WHICH IS THE NEXT SET OF BARS. IN THAT AREA WE WERE ALLOCATED A TOTAL OF $7,171,000. AS OF JUNE 30TH, WITHOUT ACCRUALS OR LAGS, WE HAVE RECORDED EXPENDITURES OF $4,559,000, OR 64 PERCENT OF THAT ALLOCATION, LEAVING A BALANCE OF $2,611,000.

SO OVERALL OUR BUDGET WAS 16 MILLION. WE'VE RECORDED ALMOST 13 MILLION OF EXPENDITURES, LEAVING APPROXIMATELY 3 MILLION FOR ACCRUALS AND LAGS AND A BALANCE BASICALLY. WE ANTICIPATE THAT A BIG CHUNK OF THAT 3 MILLION WILL ACTUALLY RESULT IN LAGS AND ACCRUALS. BUT BECAUSE OUR FINANCIAL STATEMENTS JUST CLOSED OFF AT THE BEGINNING OF THIS WEEK, WE JUST GOT THE FINANCIAL STATEMENTS YESTERDAY AFTERNOON. AND SO I DIDN'T HAVE A CHANCE TO

FINALIZE THIS REPORT SO THAT I COULD GIVE YOU A FINAL JUNE 30TH. BUT AT OUR NEXT BOARD MEETING, I WILL BE ABLE TO DO THAT.

ARE THERE ANY QUESTIONS? OKAY. THANK YOU.

CHAIRMAN THOMAS: DOES THAT CONCLUDE YOUR REPORT, ALAN? THANK YOU VERY MUCH.

MR. TORRES: MR. CHAIRMAN, I JUST WANTED TO HIGHLIGHT THREE ISSUES. NO. 1, THE BRIDGES PROGRAM HAS RECEIVED TREMENDOUS SUPPORT FROM THE LEGISLATURE AND I KNOW THE GOVERNOR'S OFFICE. AND THE TREMENDOUS IMPACT THESE YOUNG PEOPLE ARE HAVING IS JUST -- I WANT TO MAKE SURE THAT EVERYBODY ON THE BOARD, AND MANY OF YOU DO ALREADY, UNDERSTAND THE IMPACT THAT THIS IS HAVING AND WILL HAVE ON CALIFORNIA ON HOW WE ARE TAKING A LEAD MORE THAN ANY OTHER AGENCY IN THIS STATE TO CREATE AND TO PROMOTE YOUNG SCIENTISTS AS THEY'RE APPROACHING THEIR FUTURE AND, QUITE FRANKLY, OURS.

I ALSO WANT TO THANK AMY ADAMS AND TODD FOR THE INTERVIEWS THAT THEY CONDUCTED. I KNOW LEEZA GIBBONS AND I SHARED THOUGHTS ABOUT THE VIDEOS, WHICH WERE JUST TERRIFIC, FROM YOUNG PEOPLE TALKING DIRECTLY TO THE CAMERA. WE NEED TO EXPOSE THAT MORE IN TERMS OF WHAT WE'RE DOING.

THE CREATIVITY AWARDS, MANI AND THOSE WHO WORKED ON THAT SO HARD, IS AGAIN A REFLECTION OF WHERE WE NEED TO CONTINUE TO GROW. THE *SACRAMENTO BEE* DID A STORY ON THE ISSUES. I THINK AT SOME POINT WE OUGHT TO PUT THESE YOUNG PEOPLE IN FRONT OF THE GOVERNOR AND TEST HIS KNOWLEDGE. I THINK HE WOULD BE APPROPRIATELY CHALLENGED AND WOULD LOVE THE OPPORTUNITY, QUITE FRANKLY, KNOWING JERRY AS WELL I DO. I THINK THAT'S GOING TO BE GREAT.

ON A SIDE NOTE, YOU KNOW, THE WORLD HEALTH ORGANIZATION REPORTED THAT 32.5 PERCENT OF WOMEN IN DEVELOPING NATIONS ARE INFERTILE. AND WHAT DOES THAT MEAN? THE CONSEQUENCES ARE TREMENDOUS. IT INCLUDED THE REJECTION OF WOMEN BY THEIR OWN COMMUNITIES BECAUSE THEY COULDN'T HAVE CHILDREN. DOMESTIC VIOLENCE AND THE SPREAD OF HIV BY PROMISCUOUS HUSBANDS IN THEIR BID TO HAVE CHILDREN.

MANY OF YOU MAY NOT KNOW, BUT DR. HAMMERBERG, WHO'S A LITTLE BIT RELATED TO ALAN TROUNSON, AND ALAN AND OTHERS HAVE SPEARHEADED A FOUNDATION IN THE THIRD WORLD TO MAKE THINGS BETTER FOR WOMEN WHO ARE INFERTILE IN THE DEVELOPING WORLD. I JUST WANT TO GIVE KUDOS TO THE GOOD DR. KAREN HAMMERBERG AND OBVIOUSLY TO YOU, ALAN, FOR THIS TREMENDOUS HUMANITARIAN WORK IN AN AREA THAT REALLY

NEEDS TO BE ADDRESSED AND COURAGEOUSLY SO, I MIGHT ADD.

(APPLAUSE.)

CHAIRMAN THOMAS: THANK YOU, SENATOR TORRES. I WANTED TO JUST DO A TWO-SECOND FOLLOW-UP. ALAN REFERENCED THE IOM REVIEW. I JUST WANTED MEMBERS OF THE BOARD TO KNOW THE PRINCIPAL LIAISON WITH IOM IS LYNN HARWELL, WHO'S DOING GREAT WORK THERE, AS WELL AS BEING SORT OF THE PERSON PROVIDING ALL OF THE CRITICAL MATERIAL TO THE DEPARTMENT OF FINANCE AND THE STATE TREASURER'S OFFICE THAT IS ENABLING OUR DISCUSSIONS TO BEST MAKE OUR CASE FOR CONTINUED MAXIMUM FUNDING. SO, LYNN, THANK YOU VERY MUCH.

(APPLAUSE.)

CHAIRMAN THOMAS: WE HAVE NEXT A COUPLE OF PATIENT ADVOCATES WHO WOULD LIKE TO SPEAK TO US, AND I WOULD LIKE TO INVITE -- I HOPE I HAVE THIS IN THE RIGHT ORDER, MELISSA -- RICH. FIRST WE HAVE RICH LARSEN FROM THE HUNTINGTON'S DISEASE SOCIETY OF AMERICA.

MR. LARSEN: THANK YOU VERY MUCH AND GOOD MORNING, EVERYBODY. IT'S NICE TO SEE MANY OF YOU AGAIN. JON, CONGRATULATIONS ON THE NEW APPOINTMENT, AND WE LOOK FORWARD TO WORKING WITH YOU AS WE GO

FORWARD.

I'M A HUNTINGTON'S SOCIETY PATIENT ADVOCATE. AND WE'VE BEEN WORKING VERY CLOSELY WITH CIRM FOR QUITE SOME TIME TO DEVELOP A RELATIONSHIP AND GET SOME STUDIES FUNDED SPECIFICALLY FOR DR. JAN NOLTA UP IN UC DAVIS.

THROUGH THAT PROCESS I REALLY HAVE TO RECOGNIZE AS ONE OF YOUR FIRST PUBLIC SPEAKERS THE LEADERSHIP THAT BOB KLEIN HAS PROVIDED TO CIRM AND REALLY GIVEN HOPE TO SO MANY PATIENTS, NOT JUST IN THE HUNTINGTON'S SPACE.

THE REASON I'M HERE TODAY, THOUGH, IS PRIMARILY TO THANK YOU FOR THE VOTE THAT I BELIEVE YOU'RE TAKING AND WILL PASS, WHICH IS AN MSC, A MESENCHYMAL STEM CELL STUDY, THAT DR. JAN NOLTA IS CONDUCTING UP AT UC DAVIS. I UNDERSTAND THE STUDY HAS SCORED VERY WELL, AND THAT THERE WILL BE, IT SOUNDS LIKE, A VOTE IN THE AFFIRMATIVE WILL BE DONE THIS AFTERNOON. SO I APPRECIATE YOUR ACCOMMODATING MY SCHEDULE. I COULDN'T BE HERE AFTER THE VOTE, SO I WANTED TO THANK YOU PREMATURELY. SO I HOPE THAT IT'S NOT FOR NAUGHT.

BUT I AM AT RISK FOR HD, MY CHILDREN ARE AT RISK, MY GRANDSON IS AT RISK, AND I HAVE SEVERAL FRIENDS ALSO THAT ARE AT RISK. WE THINK THAT THIS

STUDY IS ONE OF THE TRUE HOPES THAT WE HAVE OTHER THAN EATING BLUEBERRIES FOR BREAKFAST IN THE MORNING, THAT HUNTINGTON'S DISEASE PEOPLE AT RISK ACTUALLY HAVE OF SOLVING THIS PROBLEM.

AND SO I WANTED TO EXTEND PERSONAL THANKS TO THIS BODY FOR APPROVING THIS STUDY, BUT I THOUGHT YOU SHOULD ALSO KNOW THAT THERE ARE SEVERAL ADVOCATES, TENS OF THOUSANDS ACROSS THE COUNTRY, THAT WOULD SHARE IN THESE THANKS. MY FRIEND LES HERE, HIS WIFE PASSED OF HD FAIRLY RECENTLY, A LONG AND DIFFICULT DISEASE. AND NOW HE HAS A SON AND A GRANDSON ALSO AT RISK FOR HD. I HAVE ANOTHER FRIEND RANDY. I'M LEAVING OUT THE LAST NAMES OBVIOUSLY BECAUSE THIS IS A PUBLIC MEETING. BUT HE'S LEFT A CORPORATE POSITION AS HE HAS SUNK INTO THE DEPTHS OF HUNTINGTON'S. AND HIS WIFE AND CHILDREN WATCH AS HIS DEGRADATION TAKES PLACE.

THERE ARE COUNTLESS EXAMPLES OF THIS SORT OF THING. AGAIN, WE REALLY THINK THAT THIS MSC STUDY IS SO IMPORTANT TO THERAPY AND TO GIVING HOPE TO THE HD COMMUNITY. WE REALLY APPRECIATE YOUR POSITIVE VOTE. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, RICH.

MS. KING: WE JUST HAVE A VERY BRIEF FOLLOW-UP COMMENT TO RICH'S COMMENTS, AND THEN WE'LL

BRING OUR NEXT SPEAKER UP. THANK YOU.

YI: HELLO. MY NAME IS YI. I'M A RECENT GRADUATE OF STANFORD AND A MEMBER OF THE BOARD OF DIRECTORS OF THE HUNTINGTON'S DISEASE SOCIETY OF AMERICA, A NORTHERN CALIFORNIA CHAPTER. I UNDERSTAND THE TIME IS BRIEF, SO I'D JUST LIKE TO REAFFIRM EVERYTHING RICH SAID. AS A YOUNG CALIFORNIAN, I'M VERY PROUD OF THE WORK CIRM HAS DONE. AND I'D LIKE TO REALLY GIVE YOU KUDOS FOR ALL THE WORK YOU'VE BEEN DOING FOR DISEASES SUCH AS HUNTINGTON'S DISEASE, WHICH AFFECT SO MANY PEOPLE AND SO MANY CALIFORNIANS. SO THANK YOU.

CHAIRMAN THOMAS: THANK YOU VERY MUCH. OUR NEXT SPEAKER, WHO'S WITH THE HEMOPHILIA FOUNDATION OF NORTHERN CALIFORNIA, MERLIN WEDEPOHL.

MR. WEDEPOHL: GOOD MORNING. THANK YOU FOR GIVING US A FEW MOMENTS. I'M THE EXECUTIVE DIRECTOR OF THE HEMOPHILIA FOUNDATION OF NORTHERN CALIFORNIA. WE SERVE FOLKS IN NORTHERN CALIFORNIA THAT LIVE WITH THIS CHRONIC, INHERITED, BLEEDING DISORDERS. AND WE HOPE SOMEDAY THAT WE CAN HAVE A CURE, AND YOU FOLKS MAYBE CAN HELP US.

I'D LIKE TO INTRODUCE A CARRIER OF A BLEEDING DISORDER WHO CAN TALK TO YOU JUST A FEW MINUTES ABOUT THE IMPACTS OF THE DISEASE IN HER

FAMILY. SHELLY.

MS. JAWJAY: GOOD MORNING. THANK YOU FOR HAVING ME. MY NAME IS SHELLY JAWJAY, AND I AM A MOTHER OF TWO SONS, ONE WITH HEMOPHILIA AND ONE WITHOUT HEMOPHILIA. MY 16-YEAR-OLD SON MATTHEW HAS SEVERE HEMOPHILIA.

I'M GOING TO GIVE YOU JUST A BRIEF DESCRIPTION OF WHAT HEMOPHILIA IS FOR THOSE OF YOU THAT AREN'T FAMILIAR WITH IT. HEMOPHILIA IS A HEREDITARY GENETIC DISORDER THAT IMPAIRS THE BODY'S ABILITY TO CLOT BLOOD WHICH IS USED TO STOP BLEEDING IN THE BLOOD VESSELS. FACTOR 8 IS THE MOST COMMON OF THE DISORDER, WHICH MY SON HAS, AND THERE'S ALSO A FACTOR 9. I PASSED ON THE GENE TO MATTHEW. I DID NOT PASS IT ON TO MY SON MARK.

HEMOPHILIA DOES NOT BLEED MORE INTENSIVELY IN A PERSON WITHOUT IT, BUT IT CAN BLEED MUCH LONGER. SEVERE HEMOPHILIACS, EVEN A MINOR INJURY CAN RESULT IN BLOOD LOSS LASTING DAYS OR WEEKS OR EVEN NEVER HEALING COMPLETELY. IN AREAS SUCH AS THE BRAIN OR INSIDE JOINTS, IT COULD BE PERMANENTLY DAMAGED. IT COULD CAUSE PERMANENT BRAIN DAMAGE, AND IT COULD CAUSE JOINT DAMAGE.

THERE'S ALSO ADVERSE REACTIONS TO SOME OF THE MEDICINES. SO, FOR EXAMPLE, MY SON MATTHEW IS 6

FEET 3 AND WEIGHS 220 POUNDS. SO HE'S REQUIRED TO TAKE 4500 UNITS OF A CLOTTING FACTOR TO CLOT HIS BLOOD. THIS CLOTTING FACTOR ACTUALLY COSTS ABOUT $130,000 A MONTH. AND AS MATTHEW'S WEIGHT INCREASES, SO WILL HIS DOSAGE. SOME CHILDREN DEVELOP INHIBITORS, WHICH MEANS THAT THEIR BODY REJECTS THE FACTOR THAT GOES INTO THEIR BODY, AND SO THEIR BLOOD DOESN'T CLOT AT ALL.

CURRENTLY THERE'S NO CURE FOR HEMOPHILIA. SO ANY CONSIDERATION THAT YOU CAN GIVE TO HEMOPHILIA WOULD BE GREATLY APPRECIATED, NOT ONLY BY ME, BUT BY EVERYBODY IN THE WORLD WHO SUFFERS FROM THIS DISEASE. THANK YOU SO MUCH FOR TAKING THE TIME TO LISTEN TO ME. I GREATLY APPRECIATE IT.

CHAIRMAN THOMAS: THANK YOU VERY MUCH FOR YOUR COMMENTS.

GOING TO PROCEED NOW TO ITEM 6, WHICH IS A PRESENTATION AND DISCUSSION OF CIRM'S TRANSLATIONAL GRANT PORTFOLIO. PAT, WOULD YOU PLEASE COME TO THE PODIUM? THANK YOU.

DR. OLSON: THANK YOU VERY MUCH. MR. CHAIRMAN, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC, AND COLLEAGUES, I'M LOOKING FORWARD TO UPDATING YOU ON OUR TRANSLATIONAL PORTFOLIO. THIS IS GOING TO BE AN INFORMATIONAL OVERVIEW OF OUR

CURRENT TRANSLATIONAL PORTFOLIO. ACTUALLY I LOOKED BACK. IT'S BEEN OVER 12 MONTHS SINCE WE ACTUALLY TALKED TO YOU AT ALL ABOUT THIS, SO WE THINK THE TIMING IS GOOD.

WE WANT THIS TO SERVE AS A BASIS FOR ONGOING DISCUSSIONS ON, FOR EXAMPLE, SUCH TOPICS AS PORTFOLIO PROGRAM PROGRESS, THERAPEUTIC AREA DISTRIBUTION, AND INVESTMENT. WE WANT IT TO BE BOTH A REFERENCE FOR YOU AND TO PROVIDE CONTEXT FOR BOARD DECISIONS.

ONE THING THAT I THINK IS IMPORTANT FOR YOU TO THINK ABOUT AS WE GO THROUGH THIS IS WE HAVE ACTUALLY QUITE A TRANSLATIONAL PORTFOLIO RIGHT NOW. AND THE FUNDING WE'RE PROVIDING WILL MOVE THEM FORWARD, NO QUESTION; BUT THE QUESTION IS WILL IT MOVE THEM FORWARD FAR ENOUGH TO GET PICKED UP BY INDUSTRY OR TO GET ACCEPTED AS GENERAL MEDICAL PRACTICE?

SO TO ACTUALLY THINK ABOUT, YOU KNOW, AFFECTING PATIENTS, WE HAVE TO CONSIDER WHAT IT'S GOING TO TAKE TO GET THESE THINGS TO A POINT WHERE THEY CAN ACTUALLY MOVE TO THE NEXT STEP TO MOVE FORWARD TO PATIENTS.

SO I ASK YOU TO CONSIDER FOR THOSE PROMISING, WELL-PERFORMING, AND COMPETITIVE

PROJECTS, OF WHICH THERE CERTAINLY WILL BE MANY IN OUR PORTFOLIO, WE HAVE TO CONSIDER THAT VERSUS BRINGING ON NEW PROJECTS. THESE ARE JUST DISCUSSIONS.

WHAT I'D LIKE TO DO IS THEN I WILL PROVIDE AN OVERVIEW OF THE PORTFOLIO, AND THEN ELLEN WILL GO INTO MORE DETAIL ABOUT CERTAIN PROGRAM AREAS. WHAT I WOULD LIKE TO DO BEFORE I GO FURTHER IS JUST ACKNOWLEDGE RAHAL THAKAR, A SCIENCE ASSOCIATE IN OUR OFFICE, WHO WORKED VERY CLOSELY WITH ELLEN AND I IN PUTTING THIS TOGETHER. SO I REALLY WANT TO THANK HIM AS WELL.

IF WE GO TO THE NEXT SLIDE PLEASE, LET'S BE CLEAR ON WHAT WE'RE TALKING ABOUT. THE TRANSLATIONAL PORTFOLIO IS DEFINED AS THOSE PROGRAMS THAT ARE DESIGNED TO MOVE CANDIDATE THERAPEUTICS TOWARDS AND INTO THE CLINIC. SO CURRENTLY THAT IS THOSE PROJECTS THAT ARE FOUND IN THE BOX THAT IS HIGHLIGHTED THERE. THERE ARE EARLY TRANSLATIONAL I AND II PROJECTS, THERE ARE DISEASE TEAM I RESEARCH PROJECTS, AND THERE IS OUR RECENTLY FUNDED TARGETED CLINICAL DEVELOPMENT PROGRAM.

I WANT TO REMIND YOU THAT THESE PROJECTS TARGET CERTAIN OUTPUTS. SO IF YOU LOOK AT THE STAGE-SPECIFIC BAR ABOVE, IN OUR EARLY TRANSLATIONAL

PROGRAM, WE WERE TARGETING ONE SET OF PROJECTS, FUNDS WHAT I'LL CALL PRECLINICAL PROOF OF CONCEPT. THEN PROJECTS THAT ARE BETTER FUNDED IN MANY CASES ARE TO ACHIEVE WHAT WE CALL A DEVELOPMENT CANDIDATE. IS A CANDIDATE THERAPEUTIC READY TO MOVE INTO IND-ENABLING WORK? FINALLY, OUR DISEASE TEAM PROJECTS TARGET FILING AN IND, AND OUR DISEASE TEAM I PROGRAM PROJECTS TARGETING AN INVESTIGATIONAL NEW DRUG APPLICATION WITH THE FDA. SO THIS IS TO BEGIN CLINICAL TESTING IN PEOPLE. AND THEN OUR TARGETED CLINICAL DEVELOPMENT PROGRAM ACTUALLY TARGETS COMPLETING A CLINICAL STUDY.

SO THESE ARE THE PROJECTS THAT I'M REFERRING TO WHEN I TALK ABOUT OUR TRANSLATIONAL PROGRAM.

I WANT TO JUST REMIND YOU THAT OUR TRANSLATIONAL PROGRAM IS STRENGTHENED BY PARTICIPATION OF OUR COLLABORATIVE FUNDING PARTNERS. SO OF THE PROGRAMS THAT ARE PART OF THE CURRENT PORTFOLIO, THE PARTNERS THAT ARE INVOLVED ARE THE CANCER STEM CELL NETWORK OF CANADA, CSCC, BMBF FROM GERMANY, THE STATE OF VICTORIA, AND ACTUALLY MARYLAND, WHO HAS CONTRIBUTED TO SUPPLEMENTAL FUNDING OF SOME OF OUR PROGRAMS.

WE ACTUALLY HAVE CFP PARTICIPATION

DIRECTLY INTO TEN OF OUR PROGRAMS, INTO TEN OF OUR TRANSLATIONAL PROGRAMS, AND INTO THREE AS SUPPLEMENT.

SO IF I COULD HAVE THE NEXT SLIDE, PLEASE. THE FIRST POINT I WANT YOU TO TAKE AWAY FROM THIS SLIDE IS THAT CIRM CURRENTLY HAS 44 PROJECTS IN ITS TRANSLATIONAL PORTFOLIO WITH A POTENTIAL FUNDING COMMITMENT APPROVED BY THIS BOARD OF 365 MILLION. THIS SLIDE DOES SHOW THE TIMELINE FOR GROWTH. I WOULD NOTE THAT THE ICOC FIRST AWARDED MONEY, AND I WANT TO POINT OUT HERE THAT THE YEAR IS WHEN YOU AS A BOARD APPROVED FUNDING. PROJECTS BECAUSE OF PREFUNDING ADMINISTRATIVE REVIEW TYPICALLY START THREE TO SIX MONTHS AFTER THAT.

SO THE FIRST TIME THAT THE BOARD ACTUALLY APPROVED MONEY FOR A TRANSLATIONAL PROGRAM WAS THE FIRST DISEASE TEAM PLANNING AWARDS. THAT WAS A MILLION DOLLARS IN 2008. BUT IT WAS ACTUALLY REALLY IN 2009, BASICALLY ONLY THREE YEARS AFTER CIRM FIRST FUNDED ANYTHING, THAT WE STARTED FUNDING OUR TRANSLATIONAL PORTFOLIO FOR REAL. AS YOU CAN SEE, IN 2009 THE DT I DEVELOPMENT CANDIDATE PROJECTS WERE FUNDED. THERE WERE EIGHT OF THOSE. THERE WERE 14 DISEASE TEAM I PROGRAMS THAT YOU APPROVED IN THERE. AND THEN IN 2010 YOU MAY RECALL IN OCTOBER OF LAST

YEAR YOU APPROVED THE DT II PROGRAM, BOTH PROOF OF CONCEPT STUDIES AND DEVELOPMENT CANDIDATE PROJECTS. AND THEN JUST THIS YEAR YOU APPROVED OUR FIRST EVER CLINICAL PROGRAM. SO THIS IS YEAR TO DATE.

I JUST WANT TO AGAIN REMIND YOU THAT THIS SHOWS YOU THE DISTRIBUTION OF OUTCOMES BY PROJECT AND BY DOLLARS. AS YOU GO TOWARDS -- IF YOU LOOK AT THE KEY ON THE BOTTOM, IT GOES TO THE MORE EXPENSIVE PROGRAMS, AND IT ALSO MARCHES DOWN THE STAGE-SPECIFIC PIPELINE. SO, FOR EXAMPLE, WE HAVE NINE PROJECTS THAT TARGET PRECLINICAL PROOF OF CONCEPT, AND WE'RE INVESTING ROUGHLY ALMOST 17 MILLION IN THOSE PROJECTS. AND CONTRAST THAT WITH OUR DISEASE TEAM PROGRAM WHERE WE HAVE 14 PROJECTS TARGETING AN INVESTIGATIONAL NEW DRUG APPLICATION THAT WE'RE INVESTING 225 MILLION IN. THAT'S ROUGHLY 20 MILLION -- I MEAN ON AVERAGE THEY COULD TAKE UP TO 20 MILLION IN THAT CASE.

SO THIS HIGHLIGHTS THE FACT THAT AS THE RESEARCH MOVES DOWN THE DEVELOPMENT PIPELINE, IT BECOMES MORE EXPENSIVE, AND IT'S IMPORTANT FOR PEOPLE TO REMEMBER THAT. I WOULD NOTE ALSO THAT HERE YOU CAN SEE HERE THAT WE HAVE ROUGHLY $49 MILLION IN LEVERAGE FROM OUR COLLABORATIVE FUNDING PARTNER PROGRAMS, PARTICULARLY IN PROJECTS THAT --

WELL, ACTUALLY IN ALL STAGES EXCEPT WE CURRENTLY DON'T HAVE ANY COLLABORATIVE FUNDING PARTNER PARTICIPATION IN A CLINICAL PROGRAM, AT LEAST IN THE ONE THAT WE'VE FUNDED TO DATE. SO THAT'S WHAT I WANTED TO SAY ABOUT THAT.

NEXT SLIDE, PLEASE. I THINK IT'S IMPORTANT TO REMEMBER THAT WE HAVE INVESTED BROADLY ACROSS THE STEM CELL TYPES. SO IF YOU LOOK AT THIS GRAPH, IT HIGHLIGHTS THE FACT THAT WE HAVE INVESTED IN TISSUE OR SO-CALLED ADULT STEM CELLS. WE HAVE INVESTED IN ENDOGENOUS STEM CELLS. WE HAVE INVESTED IN CANCER STEM CELLS. BUT CERTAINLY IN KEEPING WITH OUR ORIGINAL MANDATE AND WITH THE PRIORITY THAT THIS BOARD HAS AGREED THROUGH THE CONCEPT PROPOSAL, WE HAVE ALSO FOCUSED ON PROJECTS THAT UTILIZE HUMAN EMBRYONIC STEM CELLS. AND NOW IT'S THE MORE NEWER TECHNOLOGY FOR LOOKING AT PLURIPOTENT STEM CELLS, IPSC.

SO YOU CAN SEE THAT WE INVEST NOT JUST IN PLURIPOTENT AND HUMAN EMBRYONIC STEM CELLS, BUT WE DO INVEST IN OTHER STEM CELL AND PROGENITOR TYPES.

IF I COULD SEE THE NEXT SLIDE, WHAT THIS DOES IS HIGHLIGHTS THAT IF YOU LOOK AT THE DEVELOPMENT CANDIDATE PART OF OUR EARLY TRANSLATIONAL PROGRAM COMPARED TO OUR DISEASE TEAM

OR TARGETED CLINICAL DEVELOPMENT, THAT CERTAINLY AT THE EARLY STAGE OF RESEARCH, WE'RE LOOKING AT PERHAPS THE MORE NOVEL STRATEGIES. WE HAVE MORE PROGRAMS IN IPSC THERE. WE'RE LOOKING AT SOME ENDOGENOUS EFFORTS. SO THE BREAKDOWN IS A LITTLE BIT DIFFERENT IF YOU LOOK AT THE EARLIER STAGE OF RESEARCH.

THE NEXT SLIDE, PLEASE. WHAT THIS DOES IS IT HIGHLIGHTS NOT ONLY ARE WE INVESTING IN DIFFERENT STEM AND PROGENITOR CELL TYPES, BUT WE'RE ALSO FUNDING PROJECTS THAT SPAN A WIDE VARIETY OF VERY INNOVATIVE THERAPEUTIC STRATEGIES. AND THAT'S ACTUALLY AN IMPORTANT THING TO KNOW. AND THE REASON WE'RE DOING THAT IS BECAUSE, FOR ONE THING, WE BELIEVE THAT THESE KIND OF INNOVATIVE REGENERATIVE STRATEGIES, THESE CELL THERAPIES OR GENETICALLY MODIFIED CELL THERAPIES CAN ACTUALLY OFFER OPPORTUNITIES FOR CURES RATHER THAN JUST TREATMENT OF DISEASE.

BUT THESE NEW INNOVATIVE STRATEGIES REALLY DO ENTAIL WORKING CLOSELY WITH THE FDA BECAUSE IT'S ONE THING -- THEY KNOW HOW TO -- THEY'VE HAD LOTS OF EXPERIENCE WITH MONOCLONAL ANTIBODIES. THEY'VE HAD LOTS OF EXPERIENCE WITH SMALL MOLECULES. BUT WHEN YOU START TALKING ABOUT CELLS THAT ARE NOT MINIMALLY

MANIPULATED, THAT UNLIKE BONE MARROW WHERE YOU JUST TAKE IT OUT, WASH IT, PUT IT IN A BAG, FREEZE IT, BRING IT TO A PATIENT, WASH IT, AND INJECT, THESE ARE NOT THAT. THESE ARE EXPAND, DIFFERENTIATE. SO THERE'S A LOT MORE STEPS INVOLVED, AND THESE ARE THINGS THAT THE FDA, THEY'RE DEFINITELY LISTENING TO US, BUT WE'RE ALL TALKING ABOUT IT. IT'S A NEW PATH. SO I JUST WANT TO EMPHASIZE THAT WE'RE DOING -- THAT BECAUSE OF THE KIND OF PORTFOLIO WE HAVE, IT IS CRITICAL FOR US TO KEEP A DIALOGUE GOING WITH THEM.

I WOULD ALSO NOTE THAT WE DO HAVE PROGRAMS THAT ARE FOCUSED ON THE MORE CLASSIC AREAS THAT TEND TO TARGET CANCER STEM CELLS.

IF I COULD HAVE THE NEXT SLIDE, AGAIN, THIS DOES THE SAME BREAKDOWN BY LOOKING AT THE EARLIER STAGE PROGRAMS. AND YOU CAN ACTUALLY SEE HERE IT'S NOT ALL THAT DIFFERENT.

IF I COULD HAVE THE NEXT SLIDE, PLEASE. OUR PROJECTS SPAN A VARIETY OF THERAPEUTIC AREAS. I REMIND YOU THIS IS A REFLECTION OF WHAT -- SO WE'VE BEEN VERY CATHOLIC IN OUR YOU TELL US WHAT YOU THINK IS READY. AND SO THIS REFLECTS WHAT OUR APPLICANTS HAVE SUBMITTED, WHAT OUR REVIEWERS HAVE DEEMED SCIENTIFICALLY AND PROGRAMMATICALLY MERITORIOUS, AND

WHAT YOU THE BOARD HAS BELIEVED TO BE WORTH FUNDING.

OUR INVESTMENT HERE HAS BEEN LEVERAGED, AS I NOTED BEFORE, BY CFP INVESTMENT OF 49 MILLION, PARTICULARLY IN THE CANCER AREA, BUT ALSO IN THE NEUROLOGIC AREA, IN ALZHEIMER'S DISEASE, PARKINSON'S DISEASE, IN CANAVAN'S DISEASE, AND EYE DISEASE, AND IN THE HEALING OF DIABETIC ULCERS.

I SHOULD ALSO REMIND YOU THAT THE FACT THAT THERE ARE FEWER PROJECTS OR LESSER INVESTMENT IN ONE AREA REALLY MAY MEAN WHERE THE SCIENCE IS. AS LIKELY AS NOT, IT'S WHERE THE FIELD IS AND IS READY TO GO.

AT THIS POINT I'D LIKE TO THANK YOU FOR YOUR ATTENTION AND TURN IT OVER TO ELLEN, WHO WILL CONTINUE THE DISCUSSION.

DR. FEIGAL: THANK YOU SO MUCH, PAT. I JUST WANT TO -- I'M A PC PERSON, SO I'M GOING TO GO BACK TO THE PC. AND MAYBE, MELISSA, YOU CAN PUT IT UP HERE FOR ME. BUT BASICALLY WHAT YOU'VE HEARD ABOUT IS REALLY OUR FINANCIAL INVESTMENTS IN TERMS OF WHERE CIRM IS INVESTING THEIR MONEY SINCE EARLY 2009.

AS THE INSTITUTE STARTED, AS THIS AGENCY GOT GOING, THERE WAS THE EMPHASIS ON THE FOUNDATIONAL RESEARCH, ON THE BASIC BIOLOGY, ON THE

RESEARCH LEADERSHIP, AND PUTTING THE FACILITIES TOGETHER IN WHICH THE RESEARCH COULD BE DONE. SINCE 2009 WE'VE REALLY MOVED FORWARD TO ADVANCE THAT SCIENCE TOWARDS AND INTO THE CLINIC. SO I'M NOT GOING TO RUN THROUGH EACH AND EVERY SLIDE. THIS IS REALLY A REFERENCE FOR YOU TO USE IT IN CONTEXT AS YOU'RE CONSIDERING DECISIONS THAT YOU ARE MAKING, AS INITIATIVES COME FORWARD, AND RECOMMENDATIONS COME FORWARD TO YOU TO GIVE YOU A SENSE OF WHERE WE ARE WITH OUR CURRENT FUNDING AND PERHAPS USE IT AS A TOOL, NOT THE TOOL, IN TERMS OF MAYBE HELPING US DECIDE WHAT FUTURE DIRECTION SHOULD WE GO IN.

SO THIS WAS THE FIRST OF MULTIPLE DISCUSSIONS THAT WE WOULD HAVE WITH YOU, OUR BOARD, TO TALK ABOUT WHERE WE'RE FUNDING AND WHAT ARE SOME OF THE TYPES OF THINGS THAT WE'D LIKE TO DO.

I WANT TO ALSO COMMUNICATE THAT WE'RE ACTIVELY MANAGING THE RESEARCH, THAT WE'RE WORKING IN A VERY INTERACTIVE WAY WITH THE RESEARCH TEAMS. PRIOR TO AWARDING OF ALL OF THIS FUNDING, WE'RE MUTUALLY AGREEING UPON WHAT THE PROGRESS WOULD LOOK LIKE. WHAT WOULD SUCCESS LOOK LIKE? WHAT ARE THE PROGRESS MILESTONES? WHAT ARE THE CRITERIA FOR MOVING FORWARD? AND COME TO AGREEMENT BEFORE WE EVEN LET THAT FIRST DOLLAR GET SPENT ON WHAT IT IS

WE EXPECT TO SEE. DURING THE CONDUCT OF THE RESEARCH HAVE INTERACTIVE, ONGOING DISCUSSIONS BETWEEN THE SCIENCE OFFICER AND THE RESEARCH TEAMS WITH UPDATES ON THE INTERVAL PROGRESS ON A QUARTERLY BASIS AND OVERALL ANNUAL PROGRESS UPDATES.

AND ALSO WHAT WE JUST INITIATED THIS YEAR WITH OUR DISEASE TEAMS AND OUR CLINICALLY ORIENTED TEAMS ARE CLINICAL DEVELOPMENT ADVISORY MEETINGS THAT ARE GOING TO MEET WITH ALL OF OUR 14 DISEASE TEAMS AND ANY OF OUR FUTURE FUNDED DISEASE TEAMS AND CLINICAL TRIAL TEAMS ON HOW THEY'RE DOING WITH THEIR MILESTONES OF THE KEY MILESTONES SO THAT IT'S NOT JUST INTERNAL SCIENCE STAFF WITH THEIR EXPERTISE, BUT WE'RE ALSO BRINGING IN EXTERNAL EXPERTISE TO HELP MAKE SURE THAT WE'RE DOING EVERYTHING WE CAN TO MAKE OUR RESEARCHERS AND INVESTMENT A SUCCESS. AND IF IT'S NOT GOING IN THE RIGHT TRAJECTORY, THAT WE'RE NOTICING IT EARLY AND DOING WHAT WE CAN TO DO COURSE CORRECTIONS OR MAKE REFINEMENTS.

IN ADDITION, THOUGH, TO WHAT WE FUND IN THE RESEARCH, WE'RE ALSO WORKING ACTIVELY WITH THE PATHWAY. WE'RE WORKING WITH THE FDA. WE HAVE EDUCATIONAL WEBINARS, WE HAVE ROUNDTABLES THAT WE WORK WITH THEM ON ON HOW CAN WE MOVE OUR TRANSLATIONAL PROGRAMS FORWARD. FOR EXAMPLE, WE'VE

HAD EDUCATIONAL SESSIONS ON THE CELL IMAGING ISSUES WITH TRYING TO GET THESE CELL THERAPIES INTO HUMANS. DO THE CELLS EVEN SURVIVE? IF THEY SURVIVE, DO THEY MAINTAIN THE CHARACTERISTICS THAT WE THOUGHT THEY WERE GOING TO HAVE WHEN WE PUT THEM INTO A HUMAN BEING? AND ARE THEY GETTING TO THE RIGHT ANATOMIC LOCATION SO THAT THEY CAN ACTUALLY BE FUNCTIONAL? THESE ARE CRITICAL ISSUES THAT WE NEED TO WORK ON AS WE ARE TRYING TO HELP OUR INVESTIGATORS MOVE FORWARD WITH THE RESEARCH.

WE'RE ALSO HAVING A WEBINAR EARLY NEXT MONTH ON SEPTEMBER 12TH ON TISSUE ENGINEERING AND SCAFFOLDING. THIS IS A VERY CRITICAL PLATFORM AREA TO CONSIDER. AND WE'RE GOING TO HAVE SOME EXPERTS IN THE FIELD AND THE FDA TALKING ABOUT THESE ISSUES AND TRYING TO GET THIS KIND OF PLATFORM MOVING FORWARD INTO PRODUCTS.

IN ADDITION, WE'VE HAD ROUNDTABLES TALKING ABOUT PRECLINICAL ANIMAL MODELS. WE HAVE AN UPCOMING MEETING THAT WE'LL BE ANNOUNCING SOON ON SOME OF THE IMMUNE RESPONSE ISSUES THAT WE NEED TO THINK ABOUT AS WE'RE USING ALLOGENEIC CELLS, HUMAN CELLS, AND PUTTING THEM INTO PEOPLE. AND WHAT KIND OF IMMUNE RESPONSE AND WHAT KINDS OF TREATMENTS DO WE NEED TO BE THINKING ABOUT AS WE'RE MOVING THAT

FORWARD?

SO I WANTED TO LET YOU KNOW WE'RE WORKING ON ALL THESE OTHER PATHWAYS AS WELL AS WE'RE TRYING TO MOVE OUR RESEARCH PROGRAMS FORWARD. SIMILARLY, WE HAVE ACTIVE, ONGOING INTERACTIONS, DIALOGUES, AND EDUCATION WITH OUR EARLY TRANSLATIONAL PROGRAM. THIS IS JUST A SNIPPET. WE HAVE MOST OF OUR RESEARCH, JUST TO SUMMARIZE A BIT OF WHAT PAT SAID, WE HAVE 44 TRANSLATIONAL PROGRAMS. TWENTY-NINE OF THOSE PROGRAMS ARE FOCUSED ON IDENTIFYING A DEVELOPMENT CANDIDATE OR DEVELOPING PROOF OF CONCEPT. FOURTEEN DISEASE TEAMS ARE FOCUSED ON TAKING AN IDENTIFIED CANDIDATE AND MOVING IT FORWARD TOWARDS THE CLINIC FOR THOSE FIRST-IN-HUMAN CLINICAL STUDIES. AND THEN WE HAVE ONE FUNDED AND ACTIVELY ENROLLING CLINICAL TRIAL IN PATIENTS WHO ARE PARAPLEGIC WITH A NOVEL HUMAN EMBRYONIC-DERIVED STEM CELL, AN OLIGODENDROCYTE PROGENITOR CELL. WE HAVE THREE PATIENTS ON THAT TRIAL.

SO WE'RE MOVING THE SCIENCE FORWARD BOTH IN TERMS OF THE SCIENTIFIC ADVANCES, BUT ALSO ADVANCING IT TOWARDS THE CLINIC AND INTO THE CLINIC.

THIS IS JUST A SNIPPET THAT YOU LOOK AT LATER, BUT A LOT OF OUR FUNDING IS GOING TO NEUROLOGIC DISORDERS, PARTICULARLY TO

NEURODEGENERATIVE DISEASES. THIS IS JUST A LISTING OF WHERE WE'RE PUTTING OUR MONEY IN THE NEUROLOGIC DISORDERS AREA. SO YOU CAN SEE FOR SOMETIMES YOU CAN SEE THAT SOME OF THE INJURY SEEMS TO BE THE SAME FOCUS, BUT WE'RE USING A VERY DIFFERENT APPROACH. IN THE FIRST ONE WE HAVE A PHASE I CLINICAL TRIAL USING THE HUMAN EMBRYONIC-DERIVED STEM CELLS, THE OLIGODENDROCYTE PROGENITOR CELLS. IN ANOTHER WE'RE LOOKING AT CAUDA EQUINA. WE'RE LOOKING AT VERY LOW IN THE SPINAL CORD, A PARTICULAR INJURY, AND THERE THE APPROACH IS LOOKING AT MOTIVE AND AUTONOMIC PRECURSOR NEURONS. WE'RE LOOKING AT STROKE. WE'RE LOOKING AT TRAUMATIC BRAIN INJURY.

AND ON THE RIGHT-HAND SIDE, WHAT WE'VE TRIED TO GIVE YOU IS A SNIPPET OF THE TYPES OF APPROACHES, THE STEM CELL PLATFORM THAT WE'RE USING, AND WHETHER IT'S AUTOLOGOUS OR ALLOGENEIC, WHETHER IT'S FROM THE PATIENT'S OWN BODY OR WHETHER IT'S FROM ANOTHER HUMAN BEING. AND WE'RE TRYING TO MANIPULATE THAT, USE THAT SO IT CAN BE HELPFUL IN THAT PATIENT.

MORE OF THE NEUROLOGIC DISORDERS THAT WE'RE WORKING ON, YOU CAN SEE THE BROAD SPECTRUM. WE'RE WORKING IN AMYOTROPHIC LATERAL SCLEROSIS. WE HAVE SEVERAL GRANTS IN PARKINSON'S DISEASE TRYING TO

IDENTIFY EITHER A DEVELOPMENT CANDIDATE OR A PROOF OF CONCEPT. YOU CAN SEE THE DIFFERENT APPROACHES. MANY OF THEM ARE REALLY TRYING TO LOOK AT THOSE CELLS THAT CAN DELIVER THE DOPAMINERGIC ENTITY THAT REALLY NEEDS TO BE THERE IN ORDER FOR THE NEURONS TO FUNCTION APPROPRIATELY.

WE'RE ALSO WORKING ON HUNTINGTON'S DISEASE, AS WAS ARTICULATED SO WELL EARLY TODAY. WE DO HAVE AN INTEREST AND WE ARE FUNDING DEVELOPMENT CANDIDATES LOOKING AT HUNTINGTON'S DISEASE WITH MESENCHYMAL CELLS THAT ARE ENGINEERED TO EXPRESS PARTICULAR RNA'S THAT CAN TARGET THAT MUTANT MRNA. THIS IS INJECTED INTRACRANIALLY. WE'RE ALSO LOOKING AT HUMAN EMBRYONIC-DERIVED NEURAL STEM OR NEUROPROGENITOR CELLS FOR TRANSPLANTATION.

SO THIS IS ALSO JUST SO YOU CAN SEE THE THINGS THAT WE'RE LOOKING AT, NOT JUST TODAY, BUT WHAT WE HAVE ALREADY INVESTIGATED AND HAVE ACTIVELY ONGOING.

WE HAVE CANAVAN'S DISEASE. THIS OCCURS IN INFANTS. IT'S A VERY LETHAL DISEASE. IT'S REALLY LOOKING AT THE PATIENT'S OWN CELLS TO GENETICALLY MODIFY THEM TO CORRECT THE MUTANT MUTATION IN THAT DISEASE ENTITY, CORRECTING IT AND THEN TRYING TO GIVE IT BACK TO THE PATIENT. THIS IS

AT THE VERY EARLY STAGE, THOUGH, AT PROOF OF CONCEPT. WE'RE WORKING ON AUTISM. WE'RE WORKING ON REFRACTORY EPILEPSY AND ON SPINAL MOTOR ATROPHY.

ANOTHER LARGE PART OF OUR PORTFOLIO IS IN EYE DISEASES. HERE YOU CAN SEE WE HAVE FIVE DIFFERENT AWARDS TO THE TUNE OF ABOUT 34 MILLION, AND THREE OF THESE THERAPEUTIC AREAS ARE LOOKING AT MACULAR DEGENERATION. THIS IS A CLINICAL ENTITY THAT INCREASES WITH AGE. IT'S A MAJOR CAUSE OF BLINDNESS. WE REALLY HAVE NO TREATMENT FOR THE DRY MACULAR DEGENERATION. IN ADDITION, WE'RE LOOKING AT CORNEAL INJURY AND ALSO WITH GENETICALLY INHERITED DISEASE CALLED RETINITIS PIGMENTOSA, WHICH ALSO CAUSES BLINDNESS.

SO THIS IS OUR PORTFOLIO OF EYE DISEASES. ONCE AGAIN, I'M NOT GOING TO GO THROUGH THEM ONE BY ONE, BUT YOU CAN SEE THE GOAL. WE'RE EITHER LOOKING AT PROOF OF CONCEPT, WE'RE LOOKING AT A DEVELOPMENT CANDIDATE, OR WE'RE LOOKING AT A DISEASE TEAM WHOSE GOAL IS TO ACTUALLY MOVE THIS INTO THE FIRST-IN-HUMAN CLINICAL TRIALS. WE HAVE A TEAM WORKING ON FUNCTIONALLY POLARIZED HUMAN EMBRYONIC-DERIVED STEM CELLS WHERE IT'S TRYING TO REPLACE THAT RETINAL PIGMENT EPITHELIAL MONOLAYER AT THE BACK OF THE EYE. THEY'RE IMPLANTING THESE CELLS

ONTO A SCAFFOLD, AND THEY'RE GOING TO SURGICALLY IMPLANT THESE BELOW THE RETINA. AND THIS IS ON ITS WAY. THEY'RE AT THEIR 12- TO 18-MONTH MILESTONE RIGHT NOW IN A FOUR-YEAR AWARD, BUT THIS IS MOVING FORWARD.

WE ALSO HAVE AUTOLOGOUS APPROACHES, ONCE AGAIN, LOOKING AT RETINAL PIGMENT EPITHELIAL CELLS. AND THEN YOU CAN SEE THE VARIETY OF OTHER APPROACHES THAT WE'RE USING WITH DIFFERENT SPECTRUM OF EYE DISORDERS WHICH CAUSE BLINDNESS. SO THIS IS A VERY IMPORTANT DISEASE AREA FOR US TO BE LOOKING IN.

CANCER IS ALSO MAKING UP A LARGE PORTFOLIO OF WHERE CIRM IS CURRENTLY INVESTING. SO THERE ARE EIGHT DIFFERENT AWARDS TO THE TUNE ABOUT $107 MILLION FOCUSED ON CANCER. FOUR OF THEM IN THE LIQUID TUMORS, THE LEUKEMIAS, THE CHRONIC AND THE ACUTE, FOR A VARIETY OF DIFFERENT TYPES OF SOLID TUMORS, WITH OVARIAN CANCER, WITH COLON CANCER, WITH GLIOBLASTOMA.

THIS, ONCE AGAIN, IS JUST SHOWING YOU THE DIFFERENT DISEASES THAT WE'RE LOOKING AT, WHERE WE ARE IN THE PRODUCT DEVELOPMENT SCHEME. ARE WE EARLY AT IDENTIFYING A DEVELOPMENT CANDIDATE? ARE WE FARTHER ALONG IN TRYING TO MOVE IT FORWARD TO THOSE FIRST-IN-HUMAN TRIALS?

YOU CAN ALSO SEE WE HAVE A VARIETY OF PLATFORMS HERE PAT MENTIONED. WE'RE GOING WHERE THE SCIENCE IS IN TERMS OF THE STEM CELL APPROACH, BUT YOU CAN SEE THIS HAS REALLY BEEN AN EXPLORATORY PHASE FOR CIRM. WE'RE LOOKING AT A LOT OF DIFFERENT APPROACHES HERE. WE'RE LOOKING AT SMALL MOLECULES, WE'RE LOOKING AT MONOCLONAL ANTIBODIES IN THESE VARIETY OF APPROACHES. ALL OF THEM WERE EITHER ADVANCED BY STEM CELL SCIENCE OR THEY'RE TARGETING THE LEUKEMIA STEM CELL.

IN THE SOLID TUMORS, AS I SAID, THREE OF THESE ARE REALLY FOCUSED ON GETTING INTO FIRST-IN-HUMAN CLINICAL TRIALS. GLIOBLASTOMA IS REALLY A VERY LETHAL DISEASE OF THE BRAIN. THERE REALLY ARE NO GOOD THERAPIES. THERE ARE SOME FDA-APPROVED THERAPIES, BUT THEY'RE MODESTLY EFFECTIVE. WE KNOW WE NEED TO DO A LOT MORE. SO THIS IS SHOWING YOU SOME OF THE DIFFERENT APPROACHES THAT WE'RE USING TO TARGET THOSE PARTICULAR TUMORS. ALL OF THESE ARE PURPORTING TO LOOK AT THE CANCER STEM CELL. THEY'RE USING A VARIETY OF APPROACHES, EITHER SMALL MOLECULES, EITHER ALLOGENEIC, HUMAN-DERIVED NEUROPROGENITOR STEM CELLS, OR THEY'RE USING THE STEM CELL SCIENCE TO DELIVER THE CHEMOTHERAPY.

WITH THE OTHER ALSO LARGE IMPORTANCE TO CIRM'S PORTFOLIO IS IN THE AREA OF HIV/AIDS. BACK IN THE LATE '80S WHEN THE FIRST ANTIRETROVIRAL DRUG WAS DEVELOPED FOR HIV/AIDS, AIDS WAS ACTUALLY A LETHAL DISEASE. THIS WAS BACK IN THE EARLY, MID-1980S. IT WASN'T TILL 1987 THAT AZT WAS IDENTIFIED. AND THEN WITH ONGOING SCIENCE IN THE MID-1990S, THERE WERE A VARIETY OF PROTEASE INHIBITORS AND OTHER TYPES OF THERAPIES THAT WERE DEVELOPED THAT GREATLY DECREASED THE COMPLICATIONS FROM AIDS, IMPROVED THE LIFE SPAN, BUT STILL IT TURNED FROM LETHAL DISEASE THEN TO A CHRONIC DISEASE.

AND WITH THOSE DIFFERENT TYPES OF THERAPIES, THERE'S A VARIETY OF SIGNIFICANT SIDE EFFECTS THAT OCCUR. THERE'S ALSO A TREMENDOUS NEED TO BE VERY ADHERENT, VERY COMPLIANT WITH THE REGIMEN OF THESE DRUGS. IT'S A COMPLEX REGIMEN, AND RESISTANCE STILL DEVELOPS TO THE THERAPIES THAT ARE THERE.

IN 2009 THERE WAS A VERY IMPORTANT EXPERIMENT IN WHAT WE CALLED THE BERLIN PATIENT, WHO WAS A PATIENT WITH HIV/AIDS WHO ALSO HAD A MALIGNANCY. THIS PATIENT WAS TRANSPLANTED WITH CELLS FROM A DONOR WHO HAD A DELETION IN WHAT'S

CALLED CCR5 AREA OF THE GENE. THIS MUTATION IN THE GENE REALLY ALLOWS THE PERSON WHO'S CARRYING THAT GENE TO HAVE RESISTANCE TO MANY TYPES OF HIV INFECTION. THAT PATIENT STILL HAS NO EVIDENCE OF SIGNIFICANT VIRAL LOAD, AND SO IT'S CALLED CURE WITH QUOTES AROUND IT. VERY INTERESTING CLINICALLY, VERY INTERESTING SCIENTIFICALLY; HOWEVER, WE KNOW THAT THE NUMBER OF PATIENT DONORS WHO HAVE THIS CCR5 MUTATION IS GOING TO BE EXTREMELY LOW. WE NEEDED TO REALLY THINK OF ANOTHER APPROACH IN TERMS OF HOW TO SEE IF WE CAN MAKE MORE PATIENTS WITH AGE BENEFIT IN THE ATTEMPT TO GO FOR THE CURE.

CIRM IS FUNDING STUDIES AND APPROACHES TO TRY TO UTILIZE THIS VERY INNOVATIVE PILOT FINDING FROM A SINGLE PATIENT AND TRY TO THINK OF A WAY OF TRANSLATING IT INTO A WAY THAT MIGHT BE EXPORTABLE TO A BROADER POPULATION OF PATIENTS. SO WE'RE LOOKING AT TWO DIFFERENT TYPES OF APPROACHES, TRYING TO MAKE THE CCR5 DYSFUNCTIONAL SO THAT IT WON'T ALLOW HIV ENTRY.

WE'RE ALSO LOOKING IN BONE DISORDERS WITH THE USE OF ADULT PERIVASCULAR STEM CELLS AND USING A PROTEIN THAT CAN INDUCE THE BONE TO GROW UTILIZING AN ACELLULAR SCAFFOLD. WE'RE ALSO LOOKING AT OSTEOPOROSIS, A VERY COMMON DISORDER, PARTICULARLY

IN POST MENOPAUSAL WOMEN, BUT ALSO IN MEN WHO ARE TREATED WITH A VARIETY OF ENDOCRINE MANIPULATIONS FOR THEIR PROSTATE CANCER. SO WE'RE FINDING THAT COMPLICATIONS FROM OSTEOPOROSIS, NOT JUST IN WOMEN, BUT ALSO IN MEN IS BEING SIGNIFICANTLY RECOGNIZED. ALTHOUGH THERE ARE COMMERCIALLY AVAILABLE AGENTS OUT THERE RIGHT NOW, THERE ARE ATTEMPTS TO FIND OTHER APPROACHES TO TRY AND HAVE A MORE LASTING IMPACT ON THIS DISEASE.

I'M NOT GOING TO GO THROUGH ALL THESE DIFFERENT AREAS, BUT JUST TO GIVE YOU A TASTE. WE'RE LOOKING AT A VERY SIGNIFICANT PROBLEM WITH CARTILAGE DISORDERS. WHEN I FIRST CAME TO CIRM, I THINK ONE OF THE BIGGEST AREAS PEOPLE WANTED TO THINK ABOUT WERE ALL THE KNEE DISORDERS AND THE QUALITY OF LIFE ISSUES THAT COME FROM HAVING DEGENERATIVE CARTILAGE AND THE IMPACT THAT HAS ON FUNCTION. SO WE'RE WORKING IN THIS AREA.

ALSO WE'RE AT WORKING IN BLOOD AND GENETIC DISORDERS. WE'RE WORKING IN SICKLE CELL ANEMIA, AND WE'RE WORKING IN A VERY RARE TYPE OF CONGENITAL DISORDER USING AUTOLOGOUS CELLS AND GENETICALLY CORRECTING THEM AND GIVING THEM BACK TO THE PATIENT.

DIABETES AS WELL. WE'RE WORKING ON DEVELOPMENT CANDIDATES AS WELL AS IND-ENABLING

STUDIES FOR THE DISEASE ITSELF AS WELL AS FOR THE MAJOR COMPLICATION OF THAT DISEASE, CHRONIC DIABETIC FOOT ULCERS. DIABETES, AS YOU KNOW, CAN CAUSE AMPUTATIONS BECAUSE OF THE VASCULAR PROBLEMS, CAN CAUSE STROKE, HEART DISEASE. SO WE'RE WORKING ON WAYS TO TREAT THE PRIMARY DISEASE AS WELL AS THE SIGNIFICANT COMPLICATIONS FROM THE DISEASE.

AND THIS IS JUST A LISTING OF THE VARIETY OF OTHER APPROACHES THAT WE'RE USING TO LOOK AT OTHER TYPES OF MAJOR DISEASES OR INJURIES, INCLUDING DUCHENNE MUSCULAR DYSTROPHY WHERE WE'RE WORKING ON A PROOF OF CONCEPT STUDY NOW.

THE TAKE-HOME POINTS IS NOT FOR YOU TO GO THROUGH A TELEPHONE BOOK REALLY OF ALL THE DIFFERENT TYPES OF THINGS THAT WE'RE DOING, BUT WHAT WE WANTED TO GET ACROSS IS -- I THINK WHAT YOU WILL SEE IS THIS HAS BEEN AN EXPLORATION PHASE FOR CIRM. WE'VE MOVED FROM BASIC AND THE FACILITY BUILDING AND BRINGING IN RESEARCHERS TO TRYING TO MOVE US TOWARDS TRANSLATIONAL SCIENCE TOWARDS AND INTO THE CLINIC.

I THINK YOU CAN SEE FROM THE VARIETY OF THERAPEUTIC AREAS AND FROM THE VARIETY OF PLATFORMS THAT YOU SEE BEING APPROACHED THAT THIS HAS STILL BEEN THOUGHT OF AS AN EXPLORATION PHASE. AND SOME OF THE THOUGHTS AS WE GO FORWARD AS YOU THINK

THROUGH IT IS ARE WE AT A POINT IN TIME TO THINK ABOUT SOME OF THE PRIORITIZATION AND FOCUS ISSUES IN TERMS OF MAKING SURE WE GET TO OUR MISSION IN MEETING OUR DELIVERABLES OF PROVIDING THOSE PRODUCTS THAT SHOW SOME PRELIMINARY EVIDENCE OF EFFICACY.

WE HAVE MADE SUBSTANTIAL PROGRESS IN STRENGTHENING AND EXPANDING THE PORTFOLIO, THE TRANSLATIONAL PORTFOLIO, OVER THE PAST 18 TO 24 MONTHS. AND THIS IS REALLY IN VERY LARGE PART, I'D LIKE TO ACKNOWLEDGE OUR PRESIDENT, ALAN TROUNSON, WHO REALLY GOT THE AGENCY TO START FOCUSING ALONG WITH OBVIOUSLY THE RECOMMENDATIONS AND THE OVERSIGHT FROM THE BOARD INTO MOVING INTO THIS DIRECTION, THAT WE'VE MADE INVESTMENTS IN THE NUMBERS, IN THE DOLLARS OF THE PROGRAMS MOVING TOWARDS AND INTO CLINICAL TRIALS, AND THAT WE'RE WORKING COLLABORATIVELY, AS WAS MENTIONED EARLY, WITH NINE DIFFERENT COUNTRIES, WITH TWO DIFFERENT INTERNATIONAL STATES, WITH OTHER STATES ACROSS THE U.S., AND WITH PATIENT FOUNDATIONS TO LEVERAGE OUR EXPERTISE AND RESOURCES.

WE KNOW WE'RE NOT GOING TO DO IT ALONE, BUT WE'LL BE ABLE TO LEVERAGE IN A MORE EFFECTIVE WAY IF WE WORK COLLABORATIVELY WITH THESE OTHER FUNDING PARTNERS. WE'RE FORGING INTERACTIONS WITH

THE AGENCIES THAT ARE SO CRITICAL FOR DECIDING WHETHER TO APPROVE THESE THERAPIES GOING FORWARD AND WAYS TO MAKE THE REGULATORY PATHWAY MORE PREDICTABLE BECAUSE PREDICTABILITY IS GOING TO BE VERY IMPORTANT AS WE WORK WITH COMPANIES AND INVESTORS. IT'S NOT JUST GREAT SCIENCE. THERE HAS TO BE A PATHWAY FORWARD. AND WE'RE RECOGNIZING THAT EARLY AND WE'RE WORKING WITH IT.

AND ALSO ACTIVE MANAGEMENT OF THE RESEARCH PROGRAMS, PARTICULARLY IN THE TRANSLATIONAL PORTFOLIO, IS GOING TO BE, I THINK, A VERY IMPORTANT, CRITICAL ELEMENT AS OPPOSED TO PERHAPS EARLIER IN RESEARCH AND BASIC BIOLOGY WHEN WE MAY WANT TO HAVE A THOUSAND FLOWERS BLOOM. AS WE'RE MOVING TOWARDS THE CLINIC, IT'S THE GREAT IDEA, IT'S THE EXPERIENCED TEAM, AND IT'S A PATHWAY FORWARD THAT'S GOING TO ENABLE US TO EXECUTE ON OUR MISSION.

SO WITH THAT, I'D LIKE TO END AND HOPE THAT WE'VE GIVEN YOU, BOTH PAT AND I, AND I'D LIKE TO ACKNOWLEDGE IN ADDITION TO RAHAL, WE'VE WORKED EXTENSIVELY WITH THE WHOLE SCIENCE TEAM, WITH MICHAEL YAFFE, WITH BETTINA STEFFAN, WITH ALL THE SCIENCE OFFICERS IN TERMS OF TRYING PROVIDE YOU AN INFORMED SET OF SLIDES THAT WE HOPE WILL BE USEFUL TO YOU. SO THANK YOU, AND PERHAPS WE CAN OPEN THIS

UP TO QUESTIONS IF YOU ARE INTERESTED.

DR. PIZZO: THREE COMMENTS. FIRST, THANKS TO PAT, ELLEN, AND ALAN FOR THE PRESENTATION. I THOUGHT THIS WAS REALLY VERY HELPFUL AND VERY IMPORTANT.

I THINK THE SECOND, WHICH IS REALLY A FOLLOW-UP TO THE FIRST, IS AS THIS MATURES, IT WOULD BE HELPFUL TO COME BACK AND ACTUALLY IN SOME WAY HAVE GREEN, RED, AND YELLOW SIGNALS ABOUT WHERE THESE VARIOUS PROJECTS ARE SO YOU CAN SEE WHERE WE'RE HEADING IN TERMS OF YOUR COMMENTS TOWARDS SUCCESS.

THE THIRD, AND I THINK, ELLEN, YOU TOUCHED ON THIS, BUT I WANT TO UNDERSCORE AT LEAST MY VIEW ABOUT THIS, WHICH IS THERE IS A SORT OF TENSION THAT WILL LIKELY ARISE AS YOU LOOK IT A PORTFOLIO BETWEEN ARE WE COVERING EVERYTHING OR FOCUSING ON THE THINGS THAT ARE LIKELY TO LEAD TO PAYOFF. MY OWN SORT OF PERSONAL PLEA IS THAT WE AVOID THE FORMER IN FAVOR OF THE LATTER. BY THAT I MEAN I THINK ALL THE ATTENTION SHOULD BE ON WHAT AREA IS LIKELY TO LEAD TO A PROOF OF PRINCIPLE RATHER THAN SAYING DO WE HAVE SOMETHING IN THIS AREA OR NOT.

I WELL APPRECIATE THE SENSE OF NEED THAT ANY PATIENT OR PATIENT GROUP MAY FEEL ABOUT THEIR

AREA BEING COVERED, BUT THE SELECTION SHOULD REALLY AT THIS CRITICAL JUNCTURE IN TIME BE ON WHAT'S GOING TO GIVE US THE LEAD TO REALLY CARRY THIS WORK FORWARD SO ALL OF IT DOESN'T GET TRUNCATED AS THE FUNDING CYCLE GETS COMPLICATED.

DR. FEIGAL: ONE THING I JUST WOULD LIKE TO SAY IS WE INTEND TO PUT THIS UP ON OUR PUBLIC WEBSITE. WE WANT THE PUBLIC TO KNOW WHAT WE'RE FUNDING AND WHERE WE ARE FUNDING. WE WANT OUR INVESTIGATORS TO KNOW WHAT WE'RE FUNDING AND WHERE WE'RE FUNDING. AND NOW WITH OUR INITIATIVES, AND IT STARTED WITH EARLY TRANSLATION III AND IS GOING TO CARRY FORWARD INTO DISEASE TEAM II RESEARCH AWARD, WE'RE GOING TO PUT OUR PORTFOLIO UP THERE. AND IN THE RFA WE'RE ASKING IF THEY ARE LOOKING AT AN AREA WE'RE ALREADY FUNDING, PLEASE PROVIDE IN YOUR APPLICATION THE COMPELLING EVIDENCE FOR YOUR APPROACH. SO AT LEAST -- WE'RE NOT RESTRICTING IT. WE'RE JUST DRAWING PEOPLE'S ATTENTION TO IT RIGHT NOW.

CHAIRMAN THOMAS: MICHAEL, YOU HAD A COMMENT?

MR. GOLDBERG: YEAH. I JUST WANT TO ECHO PHIL'S COMMENT. I THOUGHT IT WAS AN EXCELLENT PRESENTATION AND VERY HELPFUL. AS SOMEBODY WHO'S

WATCHED THIS EVOLVE OVER THE PAST SEVERAL YEARS, IT'S VERY HEARTENING TO SEE THE PROGRESS.

WITH RESPECT TO PHIL'S OTHER POINT ABOUT FOCUS ON PROOF OF PRINCIPLE VERSUS BEING RESPONSIVE TO DISEASE-DRIVEN NEEDS, I THINK I AGREE WITH HIM. AT THIS STAGE OF OUR EVOLUTION, I THINK THAT'S CRITICAL, AND I KNOW YOU'RE MINDFUL OF THAT. THE CLINIC WILL TAKE CARE OF ITSELF IF THE SCIENCE FIRST DEMONSTRATES VIABILITY.

AND I LOOK FORWARD TO YOUR UPDATED SCIENTIFIC STRATEGIC PLAN AND THE FIT BETWEEN HOW YOU BALANCE ALL THESE DIFFICULT AND COMPELLING INITIATIVES WITH, ALTHOUGH SEEMINGLY LARGE AMOUNT OF CAPITAL, MUCH LESS CAPITAL THAN, IN FACT, THE OPPORTUNITIES SUGGEST FUNDING FOR. SO THANK YOU ALL VERY MUCH FOR THAT. AND THANK YOU TO THE WHOLE SCIENCE STAFF AND TO THE SCIENTIFIC LEADERSHIP TEAM FOR BRINGING US THIS UPDATE TODAY.

CHAIRMAN THOMAS: SENATOR TORRES.

MR. TORRES: AS A FORMER POLICYMAKER, THIS IS AN EXTRAORDINARY DOCUMENT. EVERY VOTER IN CALIFORNIA SHOULD GET A COPY OF THIS DOCUMENT IF WE COULD AFFORD IT BECAUSE IT GIVES THEM A SENSE THAT WE ARE MOVING TOWARD ACHIEVING THEIR DREAMS AND HOW THEY VOTED IN 2004. AND I THINK THAT THE LEADERSHIP

OF OUR CHAIRMAN EMERITUS, WHO'S HERE, PROVIDED THAT INITIAL SHOCK TO GET THIS THING DONE, WITH ALAN WORKING ON IT, WITH YOU, ELLEN, JOINING US, AND, OF COURSE, PAT AND THE SCIENTIFIC STAFF. I JUST WANT TO SAY THANK YOU BECAUSE I KNOW PAT'S E-MAILING IT TO ME RIGHT NOW, AND I'M GOING TO E-MAIL IT TO THE GOVERNOR'S OFFICE AS SOON AS SHE E-MAILS IT TO ME SO THAT THEY KNOW EXACTLY WHAT WE'RE DOING AND HOW WE'RE GOING TO KEEP THE UPDATES.

AGAIN, I WANT TO ASSOCIATE MYSELF WITH PHIL AND MICHAEL'S COMMENTS IN TERMS OF HOW WE MOVE FORWARD, PATIENTLY OBVIOUSLY, BUT ALSO IT IS A TREMENDOUS DOCUMENT TO TAKE TO PEOPLE TO LET THEM KNOW WE HAVEN'T FORGOTTEN THE MANDATE THAT THE VOTERS PROVIDED IN 2004. THIS IS A WONDERFUL REMINDER OF THAT. THANK YOU.

DR. BRYANT: I'D JUST LIKE TO ECHO EVERYTHING THAT'S BEEN SAID. THIS IS THE MOST EXCITING PRESENTATION I'VE SEEN IN A VERY LONG TIME. AND MANY OF US, I'M SURE, ON THIS BOARD ARE ASKED TO TALK ABOUT STEM CELLS. I AM ANYWAY. I'VE GOT THREE TALKS COMING UP. THIS IS JUST -- IF I COULD GET THAT PRESENTATION, THAT WILL BE JUST PERFECT FOR ME.

DR. FEIGAL: WE'D BE HAPPY TO SHARE THAT WITH YOU.

DR. BRYANT: THAT'S INCREDIBLE. THANK YOU.

DR. PIZZO: WHY DON'T YOU GIVE IT TO ALL OF US?

DR. FEIGAL: WE'D BE HAPPY TO SHARE IT WITH YOU.

DR. PIZZO: THAT WAY WE CAN CIRCULATE IT AS WELL TO EVERY PERSON IN CALIFORNIA.

MS. FEIT: OBVIOUSLY THE PEOPLE OF CALIFORNIA ARE THE MOST IMPORTANT AUDIENCE HERE FOR THIS DOCUMENT. BUT IF THERE IS A WAY TO PUT SORT OF A LAYMAN'S SENTENCE BESIDE SOME OF THE PROGRAMS SO THAT IT'S EASILY -- IF WE DO DISTRIBUTE IT -- MOST PEOPLE IN THIS ROOM UNDERSTAND WHAT WE'VE BEEN TALKING ABOUT; BUT IF WE GET IT OUT TO THE PUBLIC, IF WE COULD CREATE SOME LAYMAN TERM SENTENCES BESIDE SOME OF THE GRANTS AND SOME OF THE TARGETS, I THINK THAT WOULD BE REALLY HELPFUL.

DR. FEIGAL: WE'D BE VERY HAPPY TO WORK WITH PEOPLE WHO MIGHT BE BETTER AT SPEAKING ENGLISH THAN JARGON, AND WE'D BE VERY HAPPY TO WORK WITH THEM TO DEVELOP THAT.

MR. ROTH: SO JUST ONE SUGGESTION. IN ADDITION TO TRACKING ALL OF THE DATA THAT YOU PRESENTED, MAYBE IT WOULD BE GOOD TO ADD IF THERE'S

INTELLECTUAL PROPERTY INVOLVED, EITHER EXISTING IP OR IP THAT'S BEING PROSECUTED OR PROCESSED BECAUSE THAT'S GOING TO BE VERY IMPORTANT. WHEN I LOOK AT THIS PORTFOLIO, I KNOW THERE'S A LOT OF IP IN HERE.

AND THE SAME, ALAN, ON YOUR PRESENTATION TODAY. YOU GIVE US THESE REALLY BREAKTHROUGH PAPERS, AND IT WOULD BE NICE TO KNOW IF THE INVESTIGATOR OR THE INSTITUTION IS, IN FACT, FILING IP.

CHAIRMAN THOMAS: ADDITIONAL COMMENTS FROM THE BOARD.

MS. LANSING: I THINK THIS GOES WITHOUT ASSUMPTION. I WAS OUT FOR PART OF THE PRESENTATION, SO I DON'T KNOW IF YOU SAID THIS. BUT BECAUSE THIS IS SO GOOD AND BECAUSE WE WANT TO GET IT OUT AND BECAUSE ALL OF THE BOARD MEMBERS WILL DO OUR BEST TO DO SO AND WE WANT TO GET IT TO MEMBERS OF THE LEGISLATURE AS WELL AS THE PUBLIC, I ASSUME WE'RE DOING SOMETHING WITH THE PRESS AS WELL BECAUSE I THINK THIS IS EXACTLY WHAT THEY HAVE BEEN WAITING TO HEAR. IF YOU SAID THAT WHILE I WAS OUT, I APOLOGIZE.

DR. FEIGAL: I DIDN'T MENTION ANYTHING WITH THE PRESS RIGHT NOW, BUT WE CAN WORK ON IT. WE DO INTEND TO MAKE IT PUBLIC.

MS. LANSING: I THINK MAKING -- JUST AS A HELPFUL ASIDE, BECAUSE THE WORK SO EXTRAORDINARY AND EVERYONE IS SO PLEASED AND THIS IS WHAT THE TAXPAYERS ARE WAITING TO SEE WHAT THEIR DOLLARS WENT THROUGH, THIS IS WHAT THE LEGISLATURE IS WAITING FOR TO, AND THIS IS WHAT THE PRESS HAS PERHAPS NOT BEEN AS INFORMED OF. YOU KEEP READING THESE ARTICLES WHERE IS THE RESULTS? WHERE IS THE BEEF? NOW I THINK WE CAN REALLY ANSWER THAT. SO I THINK A FULL COURT PRESS WITH VARIOUS SELECT MEMBERS OF NEWSPAPERS AS WELL AS TELEVISION OUTLETS AND REALLY GOING ON AND SAYING THIS IS OUR UPDATE WOULD BE VERY HELPFUL. I THINK WE SHOULD REALLY COORDINATE THAT.

DR. PIZZO: SHERRY, WOULD YOU MIND JUST A FRIENDLY MODIFIER TO YOUR VERY HELPFUL COMMENT? I AGREE WITH WHAT YOU ARE SAYING. I ALSO THINK WE HAVE TO BE VERY CAREFUL NOT TO OVERSTATE WHERE WE ARE.

MS. LANSING: I AGREE.

DR. PIZZO: WHAT WE'RE REALLY SAYING IS THAT THESE ARE THINGS THAT HOLD PROMISE, WE HOPE. BUT IF WE RAISE EXPECTATIONS TOO FAR, I KNOW YOU UNDERSTAND THIS, SHERRY, BUT I JUST WANT TO BE SURE THAT WE ARE CLEAR ABOUT THAT. I THINK FINDING THAT RIGHT BALANCE OF TELLING THE STORY AS A WORK IN

PROGRESS IS REALLY THE GOAL.

MS. LANSING: THAT IS EXACTLY, PHIL, THE WAY I MEANT IT, AS A WORK IN PROGRESS BECAUSE WHAT I ALWAYS HEAR IS NOTHING IS HAPPENING. THAT'S WHAT THE -- AGAIN, THIS IS NOBODY'S FAULT, BUT CONSTANTLY I HEAR FROM PEOPLE WHO REALLY CARE. NOTHING IS HAPPENING. YOU KNOW, AND THE ANSWER IS, NO, THAT'S NOT TRUE. THERE'S A LOT HAPPENING. SO I DON'T WANT TO OFFER FALSE HOPES. I JUST WANT TO BE VERY FACTUAL AND NOT NEGATIVE, BUT JUST FACTUAL.

CHAIRMAN THOMAS: SHERRY AND DR. PIZZO, THOSE ARE EXCELLENT SUGGESTIONS. I HAVE BEEN LISTENING QUITE ENTHRALLED TO THIS PRESENTATION. I THINK THIS IS DYNAMITE STUFF. WANT TO CONGRATULATE THE STAFF ON JUST CONTINUED SUPERIOR WORK IN PURSUIT OF OUR MISSION. AND I ASSURE YOU, AS ONE WHO'S PRESSING THE COMMUNICATION EFFORT HERE, SHERRY AND DR. PIZZO, THAT THIS WILL BE THE CENTRAL FOCUS OF A MAJOR CAMPAIGN.

I WANT TO SAY SHERRY SAYS TOO OFTEN THE PUBLIC THINKS THAT SINCE WE DON'T HAVE IMMEDIATE CURES IN HAND, THAT THERE IS NO PROGRESS HERE. PROGRESS IN THE MEDICAL FIELD IS A VERY NUANCED TERM. AND THERE IS TREMENDOUS PROGRESS HERE ON ALL SORTS OF FRONTS. AND I DO THINK THE PUBLIC WOULD BE

VERY INTERESTED AND DESERVES TO HEAR WHERE THEIR TAX DOLLARS ARE GOING.

SO TO MR. JENSEN AND TO YOUR COLLEAGUES IN THE PRESS, I WOULD WELCOME COVERAGE ABOUT THE TREMENDOUS THINGS THAT WE ARE DOING IN THIS REGARD AND AVIDLY LOOK FORWARD TO YOUR ENTHUSIASTIC REPORTING ON THE SUBJECT MATTER.

I WOULD LIKE TO -- JUST ONE OTHER COMMENT WHICH I THINK WAS VERY INTERESTING, WHICH I THINK WAS MENTIONED AT A BOARD MEETING THAT PRECEDED ME. BUT WE GET ASKED ON OCCASION WHY WE'RE FUNDING MULTIPLE PROJECTS TARGETED AT THE SAME CONDITION. I'M REMINDED OF A COMMENT SOMEBODY MADE ABOUT THE 33 CHILEAN MINERS WHO WERE TRAPPED LAST YEAR, AND THE THREE DIFFERENT TUNNELS THAT WERE BEING DUG IN THE HOPES OF AT LEAST ONE REACHING THEM TO SAVE THEM AS THE WORLD WAS WATCHING. AND OBVIOUSLY ONE DID SUCCEED TREMENDOUSLY AND WAS A TOTAL SUCCESS. AND THAT'S BASICALLY WHAT WE'RE DOING HERE. WE'RE TRYING TO FIND AVENUES TO CURE THIS HOST OF TERRIBLE DISEASES, AND THERE ARE TERRIFIC PROJECTS THAT APPROACH THESE ATTEMPTED CURES FROM VARIOUS DIRECTIONS.

AND ONE OF THE GOALS OF CIRM IS TO HELP FUND THOSE IN THE HOPES THAT AT LEAST ONE OF THOSE

PER DISEASE HITS THE 33 TRAPPED MINERS UNDERGROUND. SO I JUST WANT TO SAY THAT I THINK THIS IS FANTASTIC. THIS IS WHAT WE'RE ALL ABOUT. AND CONGRATULATIONS COLLECTIVELY TO EVERYBODY INVOLVED.

DO WE HAVE ANY PUBLIC COMMENT ON THIS PRESENTATION? MR. REED.

MR. REED: YES. THIS IS EXACTLY WHAT CALIFORNIA WANTED. I WOULD MAKE A POINT ON OVERSTATING THE PROMISE. EVERYONE KNOWS THAT GROWTH IS SLOW, BUT THE INTENSITY OF THE STRUGGLE CANNOT BE OVERSTATED. THAT'S WHAT PEOPLE WANT TO KNOW. EVERY ONE OF THESE DISEASES HAS BEEN CALLED INCURABLE. BEEN TOLD NO HOPE. TO SEE THAT THERE IS SOME HOPE IS TREMENDOUS. IT'S A CANDLE IN A DARKENED CAVE. SO FIGHT FOR THAT STRUGGLE, MAKE IT DRAMATIC BECAUSE THIS IS LIFE AND DEATH FOR US. THANK YOU.

CHAIRMAN THOMAS: THANK YOU. DO WE HAVE ANY OTHER COMMENTS FROM THE PUBLIC ON THIS PRESENTATION? HEARING NONE, WE HAVE TWO OTHER PATIENT ADVOCATES THAT WOULD LIKE TO MAKE BRIEF STATEMENTS TO US. FIRST, WE HAVE WITH US THOMAS FOLLETT, WHO'S CHAIRMAN OF THE PARKINSON'S INSTITUTE AND CLINICAL CENTER.

MR. FOLLETT: GOOD MORNING. IT'S AN HONOR AND A PRIVILEGE FOR ME TO BE HERE THIS MORNING. AND

I CAN RELATE TO THE PORTFOLIO IN DIFFERENT WAYS. MY WIFE PASSED AWAY FROM LEU GEHRIG'S DISEASE. I HAVE EARLY FORMS OF MACULAR DEGENERATION AND I HAVE PARKINSON'S. SO IT'S HEARTENING TO SEE ALL THE WORK THAT'S BEING DONE. AND I CONGRATULATE CIRM FOR ALL THE FUNDING THAT THEY HAVE BEEN ABLE TO PROVIDE FOR THESE DISEASES.

I'VE HAD PD FOR TEN YEARS, BUT I CONSIDER MYSELF ONE OF THE LUCKY ONES. MY PROGRESSION HAS BEEN SLOW, THE MEDS WORK, AND I ENJOY ONE OF MY PRIMARY MEDICATIONS, PLAY AS MUCH GOLF AS I CAN AS PRESCRIBED BY DR. AMINOFF AT UCSF.

I'M NOT HERE TODAY FOR MYSELF EVEN THOUGH I CAN LOOK FORWARD TO THE DEGENERATIVE NATURE OF THE DISEASE WHICH WILL RESULT IN INCREASED SYMPTOMS, SUCH AS STIFFNESS IN MY WALKING, IN MY POSTURE, AS WELL AS TREMOR, AND, OF COURSE, NEW SURPRISES THAT WILL COME UP. I'M REALLY HERE FOR THE HUNDREDS OF THOUSANDS OF PEOPLE IN OUR COUNTRY AND AROUND THE WORLD WHO SUFFER FROM SEVERE PHYSICAL AND MENTAL ISSUES LIKE DEMENTIA, SPEECH PROBLEMS, INABILITY TO SWALLOW, AND CONSTIPATION. FOR PEOPLE LIKE MICHAEL J. FOX, WHO HAD EARLY ONSET IN THE PRIME OF THEIR LIFE, OR FOR THOSE WITH ATYPICAL PD, WHICH IS DIFFICULT TO DIAGNOSE AND HARDER TO TREAT.

I SEE MANY OF THESE PEOPLE EVERY WEEK WHEN I'M AT THE PARKINSON'S INSTITUTE IN SUNNYVALE WHERE I SERVE AS CHAIRMAN OF THE BOARD. I SEE YOUNG AND OLD MEN AND WOMEN SHUFFLE INTO THE CLINIC FOR THEIR TREATMENT. IT'S A GOOD REMINDER FOR ME AND FOR THE DOCTORS AND FOR THE RESEARCHERS AT THE INSTITUTE TO SEE WHAT THE DISEASE BECOMES. IT IS A STRONG MOTIVATOR TO WORK TOWARDS A CURE. AND UNTIL A CURE IS FOUND, TO PROVIDE THE BEST CARE AND TREATMENT POSSIBLE TODAY.

IT IS AN HONOR AND A PRIVILEGE TO WORK WITH DR. LANGSTON, THE FOUNDER AND CEO OF THE PARKINSON'S INSTITUTE, AND RESEARCH SCIENTISTS LIKE BIRGITT SCHULE, WHO HAS BEEN FUNDED THROUGH CIRM ON MANY GRANTS.

WE TREAT OVER 4,000 PATIENTS ANNUALLY, WE CURRENTLY RUN 25 CLINICAL TRIALS, AND WE'RE MAKING GREAT STRIDES IN FINDING EARLY DETECTION OF PD.

ADDITIONALLY, AS I HOPE YOU ARE AWARE, WE'RE MAKING GREAT STRIDES WITH STEM CELL RESEARCH WHICH HAS BEEN GENEROUSLY FUNDED THROUGH MULTIPLE CIRM GRANTS TOTALING YEAR TO DATE $7 MILLION.

WHILE THERE ARE MULTIPLE THREADS OF RESEARCH UNDER WAY, PERSONALLY I FEEL STEM CELLS PROVIDE THE BEST OPPORTUNITY FOR SUCCESS. FIRST WE

NEED TO UNDERSTAND THE MECHANISM, AND THEN WE NEED TO FIND MEDICATIONS AND TREATMENTS TO CORRECT THE CAUSES OF BRAIN CELL DEGENERATION AND ULTIMATE CELL DEATH.

THE SECOND OBJECTIVE FOR PEOPLE LIKE MYSELF IS IF THE DISEASE PROGRESSION IS STOPPED, HOW DO WE REPAIR THE DAMAGE ALREADY DONE? STEM CELLS HAVE THE POTENTIAL TO PROVIDE SOLUTIONS FOR BOTH CHALLENGES. CURRENTLY OUR LAB UNDER THE DIRECTION OF DR. BIRGITT SCHULE, WE HAVE DEVELOPED PARKINSON'S IN PETRI DISH. BECAUSE THE PARKINSON'S INSTITUTE HAS AN EXPANSIVE CROSS SECTION OF PATIENTS, WE'VE OBTAINED SKIN IN THE GAME, SO TO SPEAK, FROM OVER 50 PATIENTS, INCLUDING MYSELF, WITH VARYING FORMS OF HEREDITARY AND GENETIC FORMS OF PD. AFTER CULTURING THESE SKIN CELLS, THEY MIRACULOUSLY TURN INTO PLURIPOTENT STEM CELLS. AND I USE THE WORD "MIRACULOUSLY" BECAUSE I DON'T REALLY UNDERSTAND THE PROCESS, ONLY THE RESULT.

FROM THESE STEM CELLS WHICH CARRY A PARKINSON AS THE DISPOSITION OF THE DONOR, SUBSTANTIA NIGRA BRAIN CELLS ARE GENERATED, AGAIN MIRACULOUSLY, WHICH ARE ALIVE AND FUNCTIONING IN A PETRI DISH. ULTIMATELY OVER TIME THESE CELLS DEVELOP THE LEWY BODIES ASSOCIATED WITH PARKINSON'S

DISEASE.

FOR THE FIRST TIME EVER WE HAVE A REAL HUMAN-BASED LAB MODEL OF PD. IN THE PAST ANIMAL MODELS HAVE BEEN USED TO SIMULATE THE DISEASE. I'M ALL TOO FAMILIAR WITH THE SOD1 ALS TRANSGENIC MOUSE MODEL OR THE MTPT MODEL DEVELOPED BY OUR OWN DR. LANGSTON. WHILE THESE MODELS HAVE BEEN VERY USEFUL, THEY ARE NOT AS PRODUCTIVE OR DEPENDABLE AS DEALING DIRECTLY WITH THE HUMAN BRAIN.

WITH THIS TECHNOLOGY, WE HAVE THE OPPORTUNITY TO TEST VARIOUS GENETIC FORMS OF THE DISEASE, WHETHER IT IS A MUTATION OF THE P2 GENE OR AN OVEREXPRESSION OF ALPHA-SYNUCLEIN, WE CAN CREATE BRAIN CELLS WITH THE GENETIC FACTORS BASED ON THE INDIVIDUAL DONOR FOR OBSERVATION AND RESEARCH. AND EVEN BETTER, WE CAN STUDY THE FORMATION OF THE CELL FROM THE EARLIEST POINT; I.E., THE STEM CELLS ALL THE WAY TO THE GENETICALLY DOOMED BRAIN CELLS.

HOPEFULLY THIS RESEARCH OPPORTUNITY CAN HELP US UNDERSTAND THE DISEASE MECHANISM. AND FINALLY, WE CAN INVESTIGATE SOLUTIONS FOR PD BY TESTING DRUGS AND COMPOUNDS, DEFINE THE POSSIBILITIES TO STOP OR REVERSE THE DISEASE PROGRESSION. I HOPE AND PRAY FOR THE DAY WHEN THE DISEASE IS UNDERSTOOD AND CURED FOR THE SAKE OF MY

CHILDREN AND THE CHILDREN OF ALL PD PATIENTS SO THAT THEY DO NOT HAVE TO SUFFER THE FATE OF THEIR PARENTS.

IN ADDITION, FOR PEOPLE LIKE ME WHO HAVE LOST SO MANY BRAIN CELLS TO PD, I BELIEVE IT IS POSSIBLE TO TRANSPLANT HEALTHY BRAIN CELLS TO REPLACE THOSE LOST BY PD. BACK IN THE '90S THERE WERE TRANSPLANT PROCEDURES THAT IN A FEW CASES DEMONSTRATED DRAMATIC IMPROVEMENTS, ALTHOUGH THERE WERE MANY MORE DISASTERS THAN SUCCESSES, AND IMPROVEMENTS IN THE FORTUNATE PATIENTS WERE NOT SUSTAINED. I THINK IT SHOWS, THOUGH, THE POTENTIAL EXISTS TO TRANSPLANT PD-FREE CELLS THAT CAN REPLACE THE FAILED BRAIN CELLS AND REESTABLISH THE NETWORK OF CELLS NECESSARY FOR NORMAL FUNCTION.

THE OPPORTUNITY IS OURS TO TAKE. THE PROMISE OF STEM CELL-BASED SOLUTIONS THROUGH CONTINUED RESEARCH AND DEVELOPMENT IS AN INCREDIBLE QUANTUM LEAP FORWARD FROM WHERE WE WERE ONLY A FEW YEARS AGO. AS WITH MOST DISEASES, MONEY FOR RESEARCH IS A GATING FACTOR. COMPETITION FOR FUNDS IS DAUNTING, AS IT SHOULD BE. ARGUMENTS FOR PD PRIORITY ARE THE FOLLOWING. PD IS A DEVASTATING DISEASE WHICH AFFECTS THOUSANDS OF AMERICANS. STEM CELL RESEARCH PUTS US AT THE THRESHOLD OF FINDING A

CURE AND TREATMENT OF THE SYMPTOMS. MONEY FOR WELL-THOUGHT OUT RESEARCH APPROACHES CAN DELIVER RESULTS IN A COST-EFFECTIVE MANNER. AND FINDINGS, I THINK, AND METHODS CAN BE SYNERGISTIC WITH OTHER NEURODEGENERATIVE DISEASE SUCH AS ALS AND ALZHEIMER'S AND HUNTINGTON'S.

SO I THANK CIRM FOR ALL THE MONEY THAT YOU'VE PROVIDED, AND I LOOK FORWARD TO CONTINUED SUPPORT FOR ALL THE NEUROLOGICAL DISEASES, ESPECIALLY PARKINSON'S. THANK YOU.

(APPLAUSE.)

CHAIRMAN THOMAS: THANK YOU, MR. FOLLETT.

NEXT WE HAVE CARROLL JENKINS, THE EXECUTIVE DIRECTOR OF THE CYSTIC FIBROSIS RESEARCH INC.

MS. JENKINS: THANK YOU VERY MUCH FOR HAVING ME HERE TODAY. CYSTIC FIBROSIS OR CF IS A CHRONIC GENETIC DISEASE THAT AFFECTS THE RESPIRATORY, DIGESTIVE, AND REPRODUCTIVE SYSTEMS. MUTATIONS OF THE SPECIFIC GENE, THE CFTR, AFFECT THE TRANSFER OF SALTS AND CHLORIDES INTO AND OUT OF CELLS THAT LINE THE ORGANS OF THESE THREE SYMPTOMS. THIS DEFECTIVE GENE CAUSES THE PRODUCTION OF AN UNUSUALLY THICK AND STICKY MUCUS.

IN THE RESPIRATORY SYSTEM OF A PERSON WITH

CF, MEDICATIONS FOR LUNG INFECTIONS AND TREATMENTS TO DISLODGE THAT MUCUS ARE PART OF THE DAILY REGIMEN FOR PEOPLE WITH CF. UNFORTUNATELY AND ULTIMATELY A DECLINE IN LUNG FUNCTION CAN LEAD TO DEATH UNLESS A SUCCESSFUL LUNG TRANSPLANT CAN OCCUR.

I INVITE YOU TO MEET CHRIS. SHE'D LIKE TO BE HERE TODAY. SHE'S AT A DOCTOR'S APPOINTMENT AND WROTE THIS, "A DAY IN THE LIFE WITH CYSTIC FIBROSIS," OF WHICH I'LL READ TO YOU A PART. SHE SAYS, "I WAS DIAGNOSED WITH CF AT ONLY SIX MONTHS OF AGE. IN MY PROFESSIONAL, PERSONAL LIFE, I EARNED A BFA, WORKED A WEB LEAD AT A GRAPHIC DESIGN AGENCY, AND TAUGHT UNTIL FORCED TO RETIRE DUE TO CF COMPLICATIONS IN 2007. I'VE BEEN MARRIED FOR 11 YEARS.

"NOW AT 34 YEARS OLD CF AFFECTS PART OF MY DAY-TO-DAY LIFE. A DAY IN MY LIFE FOR ME BEGINS WITH SWALLOWING A PILL FOR ACID REFLUX AND WAITING FOR A HALF HOUR TO EAT. THEN I COUNT THE CARBS CONTAINED IN MY MEAL, TAKE MY BLOOD SUGAR WITH A PRICK OF MY FINGER TO DELIVER AN APPROPRIATE AMOUNT OF INSULIN THROUGH MY INSULIN PUMP, A PUMP THAT'S ATTACHED TO MY SKIN PRETTY MUCH ALL THE TIME AND LOOKS LIKE A PAGER. THEN I EAT BREAKFAST AND SWALLOW 12 PILLS THROUGHOUT BREAKFAST AND DO ONE

NOSE SPRAY.

"AT THIS POINT I SIT FOR A BIT AND WAIT FOR THE BREAKFAST TO SLOWLY DIGEST. THIS IS WHEN I MIGHT WATCH T.V. AND RETURN E-MAILS. I TEND TO KEEP IN TOUCH WITH FRIENDS THIS WAY BECAUSE I DO NOT OFTEN MEET PEOPLE WITH THIS DISEASE, NOR HAVE THE ENERGY TO COME OUT AND SEE THEM IN PERSON.

"TODAY AFTER BREAKFAST, I'M FEELING A LITTLE NAUSEOUS AND NEED TO SIT A BIT LONGER. THIS HAPPENS SOMEWHAT FREQUENTLY. I THINK IT'S ALL THE MEDS THAT I SWALLOW COMBINED WITH THE ACID REFLUX.

"NOW ON A RARE, EASY DAY, LIKE TODAY, WHERE I HAVE NO PLACE ELSE TO BE, I START TO FOCUS ON MY LUNG THERAPIES. THIS STARTS FOR ME WITH DOING FOUR INHALERS AND SPACING EACH OUT FIVE MINUTES APART. USUALLY I USE A TIMER AND WATCH T.V. TO DO THIS. NEXT I DO A HYPERTONIC SALINE, AN INHALED NEB DRUG THAT TAKES ABOUT 15 MINUTES. AND THIS IS THE HARDEST PART OF THE PROCESS FOR ME. THE SOLE PURPOSE OF THIS DRUG IS TO MAKE ME COUGH. DURING THE SALINE, THIS IS A BALANCE OF FINDING A PERCENTAGE THAT WILL MAKE ME COUGH, BUT NOT SO MUCH THAT I LOSE THE FOOD THAT I JUST ATE."

SHE GOES ON WITH THIS TO SAY, "AT ABOUT THIS TIME I REALIZE I HAVEN'T BEEN DOING ENOUGH NOSE

SPRAYS, SO I DO SEVEN SEPARATE NOSE SPRAYS A DAY.

"BACK TO EXERCISE. AT PULMONARY REHAB, THEY TAUGHT US TO MONITOR OUR HEART RATE, BLOOD PRESSURE, AND 02 LEVELS THROUGHOUT OUR ROUTINE, SO I DO THAT.

"AND NOW LUNCH. LUNCH IS MUCH LIKE BREAKFAST. COUNT THE CARBS, TAKE BLOOD SUGAR, DELIVER INSULIN, EAT AND SWALLOW SEVEN PILLS, AND THEN RETURN TO LUNG THERAPY."

THIS DAY IN THE LIFE OF CHRIS IS JUST HER MORNING. AND THE REST OF THIS DOCUMENT LOOKS A LOT LIKE THE MORNING. AND THIS IS FOR HER AN EASY DAY TO REMAIN HEALTHY WITH CYSTIC FIBROSIS.

CHRIS IS 34 YEARS. SHE'S A RELATIVE SUCCESS STORY AS SHE APPROACHES THE MEDIAN AGE OF SURVIVAL FOR CYSTIC FIBROSIS, WHICH IS 37. SADLY HER REPORT IS NOT SINGULAR. SHE SPEAKS FOR MANY WITH CYSTIC FIBROSIS, INCLUDING MY STEPSON ALEX, HOPE TO TURN 37 IN NOVEMBER.

IN THE UNITED STATES ONE IN 31 PEOPLE SILENTLY CARRIES THE GENE FOR CYSTIC FIBROSIS. THE MATH HAS IT THAT TWO PEOPLE IN THIS ROOM MAY BE A SILENT CARRIER AT THIS TIME FOR THIS DISEASE. WHEN THESE TWO CARRIERS HAVE A CHILD, THERE'S A ONE-IN-FOUR CHANCE THE CHILD WILL HAVE CYSTIC

FIBROSIS LIKE CHRIS, WHO LOOKS A BIT LIKE MY OWN DAUGHTER.

I ENCOURAGE CIRM TO CONTINUE THE STEM CELL RESEARCH FOR THIS LIFE-SHORTENING DISEASE. I HOPE TO SEE ON PAT'S NEXT GRAPH THAT CYSTIC FIBROSIS IS A PART OF THAT. I WANT TO THANK YOU ALL VERY DEEPLY FOR WHAT YOU ARE DOING FOR ALL OF US, ALL OF YOU, ALL OF THOSE WHO FACE CRITICAL HEALTH CHALLENGES. THANK YOU.

(APPLAUSE.)

CHAIRMAN THOMAS: SENATOR TORRES.

MR. TORRES: MS. JENKINS, I JUST WANT YOU TO KNOW THAT DURING MY RECOVERY FROM COLON CANCER IN THE HOSPITAL, MY NEXT DOOR NEIGHBOR WAS A 21-YEAR-OLD YOUNG WOMAN WITH CYSTIC FIBROSIS. I HAD NEVER HEARD OF THE DISEASE BEFORE, BUT WHAT SHE HAD TO GO THROUGH EVERY DAY EDUCATED ME PROFOUNDLY. AND I APPRECIATE THAT YOU'RE HERE.

CHAIRMAN THOMAS: THANK YOU. AND TO MR. FOLLETT AND MS. JENKINS AND THOSE THAT CAME BEFORE US EARLIER, ALL PATIENT ADVOCATES, WE HEAR YOU. WE CONTINUE TO STRIVE TO DEVELOP THERAPIES AND CURES FOR THOSE YOU REPRESENT. AND VERY MUCH APPRECIATE YOU COME TO SPEAK TO US TO FURTHER EDUCATE US ON THESE ISSUES. SO THANK YOU VERY MUCH.

WE'LL PROCEED NOW TO ITEM NO. 7.

WE HAVE A REQUEST FOR -- STRICTLY FIVE. UNDER ORDERS OF MR. HARRISON, YES, THIS IS A LEGAL ORDER, WE HAVE A FIVE-MINUTE BREAK AND WILL RESUME WITH ITEM 7. THANK YOU.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: OKAY. SCHOOL IS BACK IN SESSION HERE. WE'RE ON TO ITEM 7, WHICH IS CONSIDERATION OF RECOMMENDATIONS FROM THE GRANTS WORKING GROUP REGARDING APPLICATIONS SUBMITTED IN RESPONSE TO RFA 10-05, WHICH IS THE CIRM DISEASE TEAM THERAPY DEVELOPMENT AWARDS PART 1, OR IN ABBREVIATED PARLANCE, THE DISEASE TEAM PLANNING AWARDS.

MR. TROUNSON -- KAREN, THERE YOU ARE. YOU'RE ALREADY UP THERE. DR. KAREN BERRY IS GOING TO WALK US THROUGH THIS ITEM.

DR. BERRY: THANK YOU, MR. CHAIRMAN, BOARD MEMBERS, MEMBERS OF THE AUDIENCE, AND GUESTS TODAY. I WOULD LIKE TO PRESENT THE RECOMMENDATIONS PUT FORTH BY THE GRANTS WORKING GROUP IN MAY OF 2011 FOR THE DISEASE TEAM THERAPY DEVELOPMENT PLANNING AWARDS. THIS IS AGENDA ITEM NO. 7 IN YOUR BINDER.

IN AUGUST OF 2010, THIS BOARD APPROVED THE CONCEPT OF THE DISEASE TEAM THERAPY DEVELOPMENT

AWARD, FORMERLY CALLED DISEASE TEAM II. THE PURPOSE OF THE DTTD IS TO ADVANCE PRECLINICAL AND/OR EARLY CLINICAL DEVELOPMENT OF NOVEL THERAPIES DERIVED FROM OR TARGETING STEM CELLS OR UTILIZING REPROGRAMMING THAT MAY LEAD TO MORE EFFICACIOUS TREATMENTS FOR PATIENTS WITH DEBILITATING DISEASE OR SERIOUS INJURY.

THIS AWARD WILL OCCUR IN TWO STAGES: THE PLANNING AWARD, WHICH I WILL SPEAK TO YOU ABOUT TODAY AND PRESENT, AND THE RESEARCH AWARD. AND THE ULTIMATE GOAL OF THIS IS THAT IN FOUR YEARS TO ACHIEVE ONE OR MORE OF THESE: TO SUBMIT AN APPROVABLE IND, TO COMPLETE A PHASE I OR PHASE I/II STUDY, OR TO COMPLETE A PHASE II STUDY.

THE REASONS THE PLANNING AWARD CONCEPT CAME ABOUT WAS THIS WAS BASED ON FEEDBACK FROM OUR APPLICANTS AND FUNDING PARTNERS. AND THEY EXPRESSED THAT THEY NEED TIME AND MONEY TO ESTABLISH TEAMS WITH THE RIGHT EXPERTISE AND GATHER COLLABORATORS. SO THIS PLANNING AWARD IS SET UP TO HELP TEAMS ESTABLISH THEIR TEAMS AND GET COLLABORATORS, AND IT ALSO PROVIDES THEM OPPORTUNITY TO GET ACCESS TO REGULATORY EXPERTS, PROJECT MANAGEMENT EXPERTS, AND CLINICAL PERSONNEL SO THAT THEY CAN PUT TOGETHER THE SUPPORTING DOCUMENTS THAT THEY NEED TO CARRY OUT

THESE PARTICULAR THINGS, WHETHER IT BE AN IND OR A CLINICAL TRIAL, FOR INSTANCE, LIKE TO GET THEIR PROJECT TIMELINE READY, GET THEIR ACTIVITIES-BASED BUDGET READY, WRITE THEIR CLINICAL PROTOCOL SYNOPSIS.

WE WERE VERY CLEAR THAT WE HAD TO HAVE A SINGLE DEVELOPMENT CANDIDATE. AND THE REASON FOR THIS IS THIS IS MORE OF A READINESS ISSUE. BECAUSE IN THE TIME, THE FOUR-YEAR TIME FRAME, THAT THESE TEAMS WILL HAVE WITH THIS RESEARCH AWARD, THEY WILL HAVE TO PUT TOGETHER ALL OF THESE AND GET TO THE IND OR CLINICAL TRIAL. AND IF THEY'RE STILL TRYING TO DECIDE EARLY IN THEIR PROGRAM ABOUT TRYING TO DO A BAKE-OFF BETWEEN TWO OR THREE CANDIDATES, THEN THEY'RE NOT GOING TO HAVE ENOUGH TIME TO ACHIEVE THEIR GOALS.

SO WE WERE ALSO OPEN TO A NUMBER OF ROLES THAT STEM CELLS PLAY AND POTENTIALLY COULD PLAY IN THERAPIES. SO YOU CAN SEE ON THIS SLIDE THIS IS THE NUMBER, NUMEROUS CELL TYPES THAT WE ARE TARGETING IN THIS AWARD. AND CERTAINLY GOING FROM HUMAN EMBRYONIC STEM CELLS IN IPS CELLS, NEURAL STEM CELLS, NEUROPROGENITOR CELLS, FOR REPROGRAMMED OR GENETICALLY MODIFIED STEM CELLS, WE ALSO WILL LOOK AT PARTICULARLY SMALL MOLECULES OR BIOLOGICAL

CANDIDATES THAT WERE GENERATED USING THESE TYPES OF STEM CELLS, AS I JUST MENTIONED. CERTAINLY WE'RE TARGETING CANCER STEM CELLS OR ENDOGENOUS STEM CELLS IN VIVO AND ALSO ENGINEERED FUNCTIONAL TISSUE CANDIDATES FOR TRANSPLANTATION.

JUST TO GIVE YOU A LITTLE BRIEF REVIEW ABOUT THE CRITERIA, THE REVIEW CRITERIA IN THE GRANTS WORKING GROUP, WE CONDUCTED A FULL TWO-DAY GRANTS WORKING GROUP REVIEW WITH THE REVIEW PANEL THAT WAS MADE UP OF EXPERTISE IN AREAS OF THE VARIOUS AND SUNDRY DISEASE AREAS THAT WE HAD. WE HAD DRUG AND PRODUCT DEVELOPMENT EXPERTS. WE HAD CLINICAL TRIAL EXPERIENCED REVIEWERS. WE ALSO HAD REVIEWERS WHO HAD SIGNIFICANT EXPERIENCE IN REGULATORY AND FDA EXPERIENCE.

SO THE REVIEW CRITERIA CENTERED AROUND THESE THREE AREAS YOU CAN SEE ON THE SLIDE. IN THE SIGNIFICANCE AND IMPACT, WE LOOKED AT A DRAFT OF THEIR TARGET PRODUCT PROFILE, THE TPP. THIS WE LOOKED AT TO SEE IF THE PLAN WAS ACHIEVABLE. COULD THEY REALLY DO THIS IN FOUR YEARS? DOES IT REFLECT AN UNMET MEDICAL NEED? AND DOES IT CLINICALLY OFFER ADVANTAGES OVER THE CURRENT THERAPIES? WAS IT RESPONSIVE? ARE THEY GOING TO DO AN IND ENABLING? ARE THEY GOING TO DO A CLINICAL TRIAL?

THE PROJECT RATIONALE AND FEASIBILITY LOOKED AT, WE WANTED TO HAVE A STRONG SCIENTIFIC RATIONALE. IS THERE PRECLINICAL DATA THAT THEY HAVE THAT BACKS UP THIS? AND THEN FEASIBILITY, DO THEY HAVE ALL THE ACTIVITIES NECESSARY? HAVE THEY LOOKED AT ALL THE ACTIVITIES NECESSARY, THEIR MANUFACTURING, THEIR CLINICAL PROTOCOL SYNOPSIS, THEIR CLINICAL TRIALS PROTOCOLS, DEPENDING ON WHERE THEY ARE IN THEIR PROGRAM.

AND THEN, LASTLY, WE LOOKED AT THE QUALIFICATIONS OF THE PRIMARY INVESTIGATOR AND THE PLANNING LEADER. WHAT WE DID REQUIRE WAS THAT THE PRINCIPAL INVESTIGATOR SHOULD HAVE EXPERIENCE IN TRANSLATIONAL RESEARCH AND DEVELOPMENT.

THE PLANNING AWARD ALLOCATIONS, THE PLANNING AWARDS WHICH WE'LL DISCUSS TODAY, ARE SIX MONTHS AWARD AND THEY'RE UP TO ALLOCATIONS OF $3.3 MILLION, AND THAT WILL FUND UP TO 30 AWARDS. AND THE RESEARCH AWARDS, WHICH WE WILL HAVE LATER ON NEXT YEAR, ARE FOUR-YEAR AWARDS, AND THEY'RE UP TO $240 MILLION, AND WE'LL FUND UP TO 12 AWARDS.

NOW, THIS PARTICULAR GRAPHIC SHOWS THE DISTRIBUTION OF THE SCORES, AND IT REPRESENTS THE STARTING POINT FOR THE PROGRAMMATIC DISCUSSION THAT WE HELD AT THE GRANTS WORKING GROUP. THE FIRST

ACTION WAS TO DRAW THE GREEN LINE YOU CAN SEE OVER THERE LISTED AROUND 71, IF YOU WILL. AND THE GREEN LINE IS WHERE IT'S JUDGED TO BE -- THESE ARE JUDGED TO BE SCIENTIFICALLY MERITORIOUS AND ARE RECOMMENDED FOR FUNDING.

THE RED LINE TO THE MIDDLE OF THE GRAPH, IF YOU WILL, IS DRAWN BELOW WHICH THESE WERE LESS MERITORIOUS, AND THEY ARE NOT RECOMMENDED FOR FUNDING.

THE LINES THAT WE CREATED, THE INITIAL POINT FOR DISCUSSION WHERE ALL THE APPLICATIONS BETWEEN THE TWO BOUNDARIES, WERE SET BY THE GRANTS WORKING GROUP. THESE WERE ALL INDIVIDUALLY DISCUSSED VIGOROUSLY, I MIGHT ADD, AND WERE VOTED EITHER INTO THE TIER I, WHICH YOU SEE ON THE RIGHT, OR THE TIER III, NOT RECOMMENDED.

SO THE RESULTS OF THE PROGRAMMATIC DISCUSSION ARE SUMMARIZED ON THE FOLLOWING SLIDE. AND SO FOR TIER I, RECOMMENDED FOR FUNDING, WERE 19 APPLICATIONS, AND TIER III, NOT RECOMMENDED, WERE 17 APPLICATIONS. NOW, YOU WILL NOTICE THERE'S A LITTLE RED ASTERISK, AND THERE WERE FIVE OF THESE RECOMMENDED FOR FUNDING, WHATEVER, GRANTS THAT HAD SPECIFIC CONDITIONS. AND THESE MUST BE MET BY THE TIME OF THE RESEARCH AWARD APPLICATION DEADLINE.

AND SO THAT WAS, I MIGHT ADD, A CREATIVE WAY TO LOOK AT THIS. AND SO WE WILL ADDRESS THAT HERE BRIEFLY IN A MOMENT.

JUST TO GIVE YOU A GENERAL OVERALL TIMETABLE, THE RESEARCH AWARDS TIMETABLE, WE'RE PUTTING OUT -- THE APPLICATIONS ARE DUE IN JANUARY 2012. THE GRANTS WORKING GROUP WILL BE IN APRIL 2012. THIS BOARD WILL CONSIDER THESE IN JUNE. AND THEN THE EARLIEST FUNDING WILL BE THE SECOND HALF OF 2012.

YOU WANT TO ANSWER QUESTIONS? ANY QUESTIONS ABOUT --

DR. FEIGAL: I ACTUALLY JUST WANT TO ADD ONE THING JUST EXPLICITLY. WE HAVE AN EXCEPTIONS PATHWAY FOR FOR-PROFIT COMPANIES WHERE WE'LL CLARIFY THAT IN OUR RFA THAT WE'LL BE POSTING, THE INITIATIVE. THIS IS FOR THE AWARD, NOT THE PLANNING AWARD, THE ACTUAL RESEARCH AWARD. SO I JUST WANTED TO ADD THAT INFORMATION, THAT WE WILL HAVE A PATHWAY FOR EXCEPTIONS FOR FOR-PROFIT COMPANIES. AND ALSO FOR -- SO ANYWAY, THAT WILL BE UP TO PRESIDENTIAL DECISION. IT WILL HAVE CRITERIA LISTED THERE.

AND THIS WAS IN RESPONSE TO THE BOARD DISCUSSION WHEN THIS CONCEPT WAS FIRST DISCUSSED TO TELL US NOT JUST TO LIMIT IT TO PEOPLE WHO RECEIVED

A PLANNING AWARD, BUT BECAUSE INDUSTRY MAY HAVE A DIFFERENT TIMETABLE OR DOES NOT NEED A PLANNING AWARD, THAT WE SHOULD HAVE AN EXCEPTIONS PATHWAY OPEN TO THEM.

DR. PIZZO: REALLY A FOLLOW-UP OF THAT COMMENT. WHEN WE DID THE DISEASE AWARDS FIRST TIME AROUND, WE DID NOT HAVE AS A PREREQUISITE THAT THE SUBMITTER NEEDED TO BE A PLANNING AWARD WINNER. IS THAT STILL THE CASE THIS TIME? IF SOMEONE DIDN'T HAVE A PLANNING AWARD OR A PLANNING AWARD WASN'T FUNDED AND THE GROUP STILL DECIDED THAT THEY WANTED TO SUBMIT, WE ALLOW THAT TO HAPPEN?

DR. FEIGAL: WE ALLOW SOME EXEMPTIONS THIS TIME. SO WE DO THE RFA, DISEASE TEAM II, THE WAY IT WAS STATED, AND, GIL, PLEASE CORRECT ME IF I'M WRONG, WAS THAT IT WAS REQUIRED PLANNING AWARDS, BUT WITH EXCEPTIONS THAT COULD BE GRANTED BY THE PRESIDENT. AND ONE, THERE WAS AN EXCEPTION FOR FOR-PROFIT COMPANIES TO COME IN BECAUSE THEY HAVE A DIFFERENT TIMELINE AND MAY NOT NEED A PLANNING AWARD. AND TWO, THERE MAY BE -- WELL, FOR DISEASE TEAM I, IF THEY HAPPEN TO HAVE REACHED THEIR FINAL MILESTONE. SO IF THEY FILED THEIR IND, THEN THEY'RE ELIGIBLE TO COME IN THIS ROUTE AS WELL.

DR. PIZZO: BUT WHAT IF A GROUP WAS NOT

SUPPORTED THROUGH A PLANNING AWARD THIS TIME ROUND, BUT IT WAS STILL VIEWED BY THE TEAM THAT THEY HAD AN IMPORTANT PROPOSAL AND THROUGH ANOTHER FUNDING SOURCE, NOT CIRM, THEY DECIDED THAT THEY WERE GOING TO GO AHEAD AND MAKE A SUBMISSION? WILL THAT BE ENTERTAINED OR NOT?

DR. FEIGAL: WE STILL HAVE THAT EXCEPTION PATHWAY. SO ARE YOU TALKING ABOUT THEY WENT THROUGH THE PROCESS AND --

DR. PIZZO: MINE IS PARTLY HYPOTHETICAL BECAUSE I DON'T KNOW THAT THERE'S A CASE I HAVE IN MIND YET, BUT I JUST WANTED TO KNOW WHAT THE OPTIONS ARE.

DR. FEIGAL: WE HAVE AN EXCEPTIONS PATHWAY.

CHAIRMAN THOMAS: I WOULD LIKE TO NOTE THAT THE PROCESS INVOLVES BOTH THE SCIENTIFIC REVIEW OF THE PROPOSAL AS WELL AS A PROGRAMMATIC REVIEW, WHICH I THINK FOR THE BENEFIT OF OUR NEW MEMBERS AND TO REFRESH THE MEMBERS OF THE PUBLIC ON THAT PARTICULAR PART OF THE PROTOCOL, PERHAPS I COULD CALL ON JEFF SHEEHY JUST TO COMMENT ON THE PROGRAMMATIC REVIEW PROCESS.

MR. SHEEHY: SURE. AND BY THE WAY, I JUST WANT TO COMPLIMENT STAFF AND THEIR LEADERSHIP IN

THIS.

NO. 1, I THINK THE EXCEPTIONS ROUTE IS VERY CREATIVE. IT GIVES ANOTHER DOOR IN. AND SO I THINK THAT'S A NICE INNOVATION IN THIS ROUND.

BUT WE HAD A VERY GOOD PROGRAMMATIC REVIEW. AND I THINK IF PEOPLE LOOK AT THE SUMMARIES, I THOUGHT THAT THIS WAS ONE OF THE MOST CREATIVE PROGRAMMATIC REVIEWS. AND I THOUGHT STAFF WAS VERY AGGRESSIVE IN TRYING TO MAXIMIZE THE UTILITY OF THE REVIEW. THEY OFFERED TO SOME OF THE GRANTEES REALLY AN OPTION, RIGHT. WHILE THEY HAD VERY GOOD PROPOSALS, SOME OF THEM SEEMED LIKE THEY WERE REALLY ON THE CUSP OF BEING EITHER AN EARLY TRANSLATION AWARD OR A DISEASE TEAM. AND THEY GAVE THEM THE OPTION OF BYPASSING THROUGH THE PROGRAMMATIC REVIEW, OBVIOUSLY WITH THE ADVICE OF THE SCIENTIST AND THE PATIENT ADVOCATES PARTICIPATING IN THE REVIEW, THE OPTION OF BYPASSING THE PREAP PROCESS, GOING DIRECTLY INTO THE EARLY TRANSLATION ROUND, WHICH I BELIEVE IS THIS FALL I THINK IS WHEN THE APPLICATIONS ARE IN.

SO THAT REALLY GIVES GRANTEES, I THINK, WITH THE ADVICE FROM WHAT I THOUGHT WAS AN EXTRAORDINARY WORKING GROUP, AS WE MOVED DOWN THE CLINICAL PATHWAY, THE ABILITY OF STAFF TO ASSEMBLE A

REALLY DIVERSE GROUP OF REVIEWERS WITH INCREDIBLE EXPERIENCE, ESPECIALLY I THINK IN THE REGULATORY SIDE, HAS JUST BEEN ASTOUNDING. AT LEAST TO ME. WE'VE GOTTEN KIND OF OUT OF THE SCIENCE AND HOW DO WE MAKE THIS WORK. SO THAT OPTION, I THINK, WAS A REALLY INTERESTING INNOVATION THAT THEY BROUGHT TO THIS PROCESS THAT THE WORKING GROUP EMBRACED.

AND I ALSO THINK THAT THE CONDITIONS THAT WERE BROUGHT. AND, AGAIN, I THINK THE DISCUSSION THAT STAFF HAS PUT TOGETHER ABOUT THE PROGRAMMATIC REVIEW, WHICH IS AT THE FIRST COUPLE OF PAGES AFTER THE SCORES, IS VERY HELPFUL TO READ THROUGH BECAUSE THERE WERE SOME QUESTIONS THAT, IF FOLKS COULD ANSWER THOSE QUESTIONS BY THE TIME THE APPLICATIONS NEEDED TO BE SUBMITTED FOR THE BIG, SO TO SPEAK, FOR THE BIG MONEY, THEY'D HAVE A GOOD SHOT AT IT. IF THEY REALLY COULDN'T GET THE ANSWER TO THESE QUESTIONS, IT REALLY WASN'T SENSIBLE FOR THEM TO THINK THAT THEY HAD AN OPPORTUNITY TO GET THIS FUNDING.

SO I DON'T KNOW HOW MUCH MORE DETAIL. I DO KNOW THAT WE HAVE SOME NEW FOLKS. WOULD IT BE HELPFUL TO KIND OF DESCRIBE HOW PROGRAMMATIC REVIEW WORKS WITH THE --

DR. FIRESTEIN: WE HAVE SOME EXPERIENCE.

MR. SHEEHY: IN GENERAL I THOUGHT THAT THIS WAS AN OUTSTANDING SESSION, AND AGAIN KUDOS TO STAFF. GREAT JOB.

DR. FEIGAL: WHAT I HAVE -- WHAT WE HAVE HANDED OUT, THE TOOL THAT YOU SAW FOR ITEM NO. 6, WHAT WE DID, IT'S NOT TO PREJUDGE HOW YOU WANT TO MAKE YOUR FINAL DECISION, BUT WHAT WE DID IS WE DROPPED IN WHERE THESE PLANNING AWARDS THAT ARE RECOMMENDED FIT IN THE PORTFOLIO. SO THE SECOND HANDOUT THAT YOU RECEIVED DURING THE BREAK DROPS IN THE RECOMMENDED PLANNING AWARDS.

CHAIRMAN THOMAS: DR. SAMBRANO, DO YOU HAVE SOME ADDITIONAL COMMENTS?

DR. SAMBRANO: NO. I THINK THIS SLIDE JUST HIGHLIGHTS THOSE THAT HAVE A CONDITION ATTACHED TO THEM. AND THEN WHENEVER YOU'RE READY, I WILL BRING UP THE PROJECTION FOR THE SET OF APPLICATIONS AND THEIR RANK ORDER.

CHAIRMAN THOMAS: I THINK BEFORE WE GET INTO THE SPECIFICS, I BELIEVE WE HAVE ONE EXTRAORDINARY PETITION WOULD LIKE TO MAKE A COMMENT HERE. PLEASE COME TO THE PODIUM. THANK YOU.

DR. SOO: THANK YOU. I WANT TO THANK CHAIRMAN THOMAS, PRESIDENT TROUNSON, AND ICOC MEMBERS FOR HEARING OUR PETITION. I AM DR. CHIA

SOO, THE PLANNING LEADER. AND I AM SPEAKING ON BEHALF OF DR. JOHN ADAMS, THE PRINCIPAL INVESTIGATOR, WHO UNFORTUNATELY COULD NOT BE HERE TODAY, AND OUR ENTIRE DISEASE TEAM ON OUR PROPOSAL TITLED "REGENERATING BONE IN PATIENTS WITH OSTEOPOROSIS."

NOW, JUST TO GIVE YOU AN IDEA OF HOW CRITICAL THIS PROBLEM IS, IF YOU TAKE A LOOK AROUND THIS ROOM, ONE IN TWO WOMEN AND ONE IN FOUR MEN AFTER AGE 50 WILL SUFFER AN OSTEOPOROTIC FRACTURE, AND FULLY HALF OF THESE FRACTURES WILL BE VERTEBRAL COMPRESSION FRACTURES IN WHICH THE OSTEOPOROTIC VERTEBRAL BODY SIMPLY COLLAPSES. UNLESS THIS COLLAPSE IS CORRECTED TO RESTORE NORMAL VERTEBRAL HEIGHT AND ALIGNMENT, PROGRESSIVE KYPHOSIS OR HUMPBACK DEFORMITY DEVELOPS THAT CAN CAUSE LONG-TERM COMPLICATIONS OF IMPAIRED LUNG FUNCTION, SEVERE PAIN, AND INCREASED DEATH.

OUR CANDIDATE PRODUCT IS THE ONLY ONE IN THE CIRM PORTFOLIO THAT IS SPECIFICALLY DESIGNED TO RESTORE VERTEBRAL HEIGHT AND ALIGNMENT AND PREVENT KYPHOSIS COMPLICATIONS BY STIMULATING THE PATIENT'S OWN STEM CELLS TO RESTORE THE LOST BONE AND FUNCTION. HOWEVER, THERE WERE SOME FUNDAMENTAL MISCONCEPTIONS IN OUR GRANT REVIEW THAT WE WANT TO

ADDRESS.

FIRST, I WILL DESCRIBE OUR CANDIDATE PRODUCT; SECOND, HIGHLIGHT OUR RESPONSE TO THE REVIEWERS' COMMENTS; AND, THIRD, PROVIDE A GENERAL SUMMARY.

AS YOU KNOW, THE FDA BROADLY REGULATES MEDICAL PRODUCTS SUCH AS A DRUG, A BIOLOGIC, OR A DEVICE. AS WE WROTE IN OUR GRANT, WE ALREADY HAVE MET WITH THE FDA, AND THEY ALREADY DETERMINED THAT OUR CANDIDATE PRODUCT WILL BE REGULATED AS A DEVICE AND NOT AS A BIOLOGIC OR A DRUG. THIS MEANS THAT OUR PROJECT WILL REQUIRE SIGNIFICANTLY LESS TIME, LESS HUMAN SUBJECT NUMBERS, AND LESS COSTS BEFORE FDA APPROVAL BECAUSE DEVICES TYPICALLY REQUIRE TWO-PHASED RATHER THAN THREE-PHASED CLINICAL TRIALS.

AND THE REASON THAT OUR PRODUCT IS A DEVICE AND ON A SHORTER FDA APPROVAL TIMELINE IS THAT THREE OF THE FOUR MAIN COMPONENTS ARE ALREADY FDA APPROVED FOR HUMAN USE AS DEVICES. SO OUR DEVICE CONSISTS OF A MESH BAG ALREADY FDA APPROVED TO HOLD BONE PARTICLES, HUMAN BONE PARTICLES, THAT ARE ALSO ALREADY FDA APPROVED, AND THE NELL BIOLOGIC PROTEIN FREEZE DRIED ONTO SYNTHETIC FDA APPROVED BONE PARTICLES.

SO EXCEPT FOR THE NELL-1 PROTEIN THAT

STIMULATES THE PATIENT'S OWN STEM CELLS, EACH OF THE THREE COMPONENTS, THAT IS, THE MESH, THE HUMAN BONE, AND THE SYNTHETIC BONE PARTICLES, ARE ALREADY INDIVIDUALLY FDA APPROVED AS DEVICES FOR HUMAN BONE DEFECTS. AND THE NELL-1 PROTEIN ITSELF IS ALREADY IN CGMP COMPLIANT PRODUCTION. SO ALL WE WANT TO DO, AS DESCRIBED IN OUR APPLICATION, IS TO COMBINE THE HUMAN BONE AND THE NELL-1 CODED SYNTHETIC BONE PARTICLES BY SIMPLE MIXING AND THEN PUTTING THAT MIXTURE IN A MESH BAG WITHIN THE COLLAPSED VERTEBRAL BODY SO THAT THE MORE WE CAN FILL THE MESH BAG WITH THE BONE PARTICLES, THE MORE WE CAN REEXPAND THE COLLAPSED VERTEBRAL BODY TO RESTORE NORMAL VERTEBRAL HEIGHT AND ALIGNMENT.

CURRENTLY THE ONLY FDA APPROVED DEVICES FOR RESTORING VERTEBRAL HEIGHT INVOLVES BALLOON INFLATION AND INJECTION OF A TOXIC CEMENT INTO THE COLLAPSED VERTEBRAL BODY. AS DESCRIBED IN OUR APPLICATION, OUR DEVICE WILL NOT ONLY RESTORE NORMAL VERTEBRAL HEIGHT AND ALIGNMENT, BUT IT WILL ALSO BE A SIGNIFICANT IMPROVEMENT OVER THE USE OF TOXIC CEMENT BECAUSE OUR DEVICE WILL USE A NELL-1 BIOLOGIC TO RECRUIT LOCAL STEM CELLS AND RESTORE THE LOST BONE.

NOW, WITH RESPECT TO THE SIX MAJOR

REVIEWERS' COMMENTS, THE WRITTEN PETITION HAS A DETAILED POINT-BY-POINT RESPONSE BASED ON INFORMATION ORIGINALLY PROVIDED IN OUR GRANT. SO IN THE INTEREST OF TIME, I'M JUST GOING TO FOCUS ON COMMENT TWO, AS IT REALLY WAS THE MAJOR CRITIQUE IN WHICH ONE REVIEW STATED THAT OUR PROPOSED COMPARISON CONTROL, WHICH IS THE BALLOON INFLATION FOLLOWED BY TOXIC CEMENT INJECTION, IT'S CALLED KYPHOPLASTY, WHICH IS THE CURRENT PRACTICE FOR RESTORING VERTEBRAL HEIGHT, WAS NOT EFFECTIVE FOR VERTEBRAL COMPRESSION FRACTURES. AS SUPPORT, THE REVIEWER CITED TWO *NEW ENGLAND JOURNAL* STUDIES.

THIS IS LIKE COMPARING APPLES AND ORANGES BECAUSE THE PROCEDURE DESCRIBED IN *NEW ENGLAND JOURNAL* DOES NOT RESTORE VERTEBRAL HEIGHT AND IS A COMPLETELY DIFFERENT PROCEDURE FROM OUR PROPOSED CONTROL, WHICH IS CALLED KYPHOPLASTY.

FURTHERMORE, THE DESIGN OF TWO *NEW ENGLAND JOURNAL* STUDIES GENERATED SIGNIFICANT CONTROVERSY AT THE TIME IN LETTERS TO THE EDITOR, AND THEIR FINDINGS WERE LATER REFUTED IN A LARGER *LANCET* STUDY WITH MORE CAREFUL EXPERIMENTAL DESIGN.

NEXT, I WANT TO STRESS THAT OUR PROPOSAL ADDS SIGNIFICANT PROGRAMMATIC DIVERSITY TO CIRM'S PORTFOLIO BECAUSE NOT ONLY IS OUR DEVICE THE ONLY

THERAPEUTIC AIMING TO RESTORE NORMAL VERTEBRAL HEIGHT AND ALIGNMENT, BUT OURS IS THE ONLY THERAPEUTIC THAT WILL BE REGULATED AS A DEVICE USING THE PMA OR PREMARKET APPROVAL PATHWAY RATHER THAN THE BLA OR BIOLOGIC LICENSE, OR NDA, THE NEW DRUG APPLICATION PATHWAYS. THIS MEANS THAT OUR PRODUCT REQUIRES LESS TIME, LESS SUBJECT NUMBERS, LESS COST, AND CAN BE ON A FASTER FDA APPROVAL TRACK, AND THUS REACH THE LARGEST NUMBER OF CALIFORNIANS SOONER.

SO IN LIGHT OF THE MAJOR MISCONCEPTION ABOUT OUR APPLICATION, AND TO INCREASE THE CIRM PORTFOLIO DIVERSITY, I RESPECTFULLY PETITION THE ICOC TO FUND OUR PLANNING AWARD OR, AT THE VERY MINIMUM, TO ALLOW US AN EXCEPTION TO APPLY FOR THE DISEASE TEAM AWARD. THANK YOU.

CHAIRMAN THOMAS: THANK YOU FOR YOUR PRESENTATION. FOLLOWING THE REPORT ON THOSE AWARDS THAT WE ARE CONSIDERING, WE'RE GOING TO BE HEADING INTO CLOSED SESSION. AND WE WILL ASK MEMBERS OF THE BOARD AT THAT POINT IF THEY ARE INTERESTED IN -- JAMES, YOU'RE SHAKING YOUR HEAD HERE.

ARE THERE MEMBERS -- I'VE JUST BEEN TOLD WE NEED TO DO IT IN OPEN SESSION. SO ARE THERE MEMBERS OF THE BOARD, HAVING HEARD THIS PRESENTATION, THAT WOULD BE INTERESTED IN TAKING

THIS MATTER UP?

DR. PRIETO: MR. CHAIRMAN, I WOULD BE INTERESTED. AND I HAVE BOTH A COMMENT AND A QUESTION.

THE FIRST COMMENT IS, AND I DON'T HAVE ANY PARTICULAR SCIENTIFIC EXPERTISE DEALING WITH VERTEBRAL COMPRESSION FRACTURE, BUT I HAVE CLINICAL EXPERIENCE DEALING WITH IT. AND I FOUND SOME OF THESE ARGUMENTS FAIRLY PERSUASIVE. VERTEBRALPLASTY INDEED IS NOT ALL THE SAME AS KYPHOPLASTY. AND THE STANDARD OF CARE CURRENTLY IS SORT OF BASED ON RELIEF OF PAIN, AND THEY'RE TRYING TO ACCOMPLISH SOMETHING MORE HERE. SO I WAS IMPRESSED THAT PERHAPS THERE REALLY WAS AN APPLES-AND-ORANGES ARGUMENT THAT WAS NOT APPARENT AT THE REVIEW.

BUT MY OTHER QUESTION WAS SINCE YOU ARE COMBINING THE BIOLOGIC WITH THE CARRIER MATRIX, DOESN'T THAT POTENTIALLY TAKE YOU OUT OF THE DEVICE APPROVAL CATEGORY?

DR. SOO: NO. IN TERMS OF THE PRIMARY MODE OF ACTION, AND IF YOU LOOK AT HISTORICALLY WHAT CDHR, THE CENTERS FOR DEVICE AND RADIOLOGIC HEALTH, HAS REGULATED, THEY REGULATE BMP II AS A DEVICE. SO AS A COMBINATION DEVICE. SO BMP II AS AN OSTEOINDUCTIVE FACTOR IS REGULATED UNDER THE DEVICE

PATHWAY. AND FOR THEIR CLINICAL APPROVAL, THEY JUST REQUIRED PILOT AND PIVOTAL STUDIES.

AND SO WE'VE ALREADY MET WITH THE FDA, AND WE SAID THIS IS WHAT OUR COMBINATION DEVICE IS. WHAT APPROVAL PATHWAY ARE WE GOING TO BE? AND THEY TOLD US IT'S GOING TO BE PRIMARILY REGULATED UNDER CDRH, SO THAT MEANS PILOT STUDIES, PIVOTAL STUDIES AS OPPOSED TO BLA'S OR NDA'S THAT REQUIRE PHASE I, PHASE II, AND PHASE III.

CHAIRMAN THOMAS: I BELIEVE DR. FEIGAL AND DR. SAMBRANO BOTH HAVE POINTS TO MAKE ON THIS QUESTION.

DR. FEIGAL: MY ONLY POINT REALLY WAS JUST IN RESPONSE TO THAT, I HAVE A LOT OF BACKGROUND WITH FDA ISSUES. AND ACTUALLY, IN GENERAL, BONE, EVEN IF IT INVOLVES CELLULAR ISSUES, IF IT'S ON A SCAFFOLD, GENERALLY GOES TO CDRH. THAT ACTUALLY ISN'T A NEW PRECEDENT. THAT'S SOMETHING THEY'VE DONE.

DR. SAMBRANO: MY COMMENT WAS MORE ABOUT THE PROCESS THAT I THINK WE'VE ADOPTED IN THE PAST IN TERMS OF EXTRAORDINARY PETITIONS. I THINK I JUST WANT TO HIGHLIGHT SOME OF THIS FOR YOUR INFORMATION.

SO WHEN WE RECEIVE AN EXTRAORDINARY PETITION, THIS IS BASED ON THE SET OF RULES THAT WERE ESTABLISHED BY THE BOARD IN ORDER FOR

APPLICANTS TO PROVIDE WHAT THEY FEEL IS AN EXTRAORDINARY CIRCUMSTANCE FOR YOU TO CONSIDER. GENERALLY, UNLESS YOU FEEL IT'S IMPORTANT OR THERE ARE ISSUES THAT YOU SHOULD CONSIDER, IT DOES NOT NECESSARILY NEED TO BE BROUGHT UP IN THE COURSE OF THE MEETING.

AND THE OTHER THING THAT WE HAVE DONE IN THE PAST THAT WE ARE NO LONGER DOING IS PROVIDING POINT-BY-POINT COMMENTS ON THE COMMENTS PROVIDED BY THE APPLICANT. SO IN OTHER WORDS, CIRM DOES NOT HAVE A SPECIFIC RESPONSE TO THESE POINTS UNLESS WE REALLY FEEL THERE IS SOMETHING THAT YOU NEED TO CONSIDER.

SO I THINK IN TERMS OF THE COMMENTS THAT WERE BROUGHT UP IN THIS PETITION, THERE ARE MANY THAT REPRESENT, I THINK, A DIFFERENCE OF SCIENTIFIC OPINION. OVERALL, IN GENERAL, THERE'S NOTHING THAT WE FEEL WOULD NOT NECESSARILY OVERCOME WHAT WAS THE RECOMMENDATION BY THE GRANTS WORKING GROUP ITSELF. I THINK SOME OF THOSE POINTS MIGHT NEED TO BE DISCUSSED IN CONFIDENTIAL SESSION DUE TO CONFIDENTIAL NATURE OF THOSE POINTS. BUT IN TERMS OF JUST THE OVERALL GENERAL PROCESS, THAT IS WHAT WE HAVE OBSERVED.

MR. HARRISON: I JUST WANTED TO REMIND

BOARD MEMBERS BECAUSE WE'RE NOW DISCUSSING A SPECIFIC APPLICATION, EACH OF YOU HAVE A SHEET IN FRONT OF YOU THAT IDENTIFIES THE APPLICATIONS THAT HAVE BEEN IDENTIFIED AS PRESENTING CONFLICTS. SO PLEASE REFRAIN FROM DISCUSSING OR PARTICIPATING IN ANY MOTION RELATING TO AN APPLICATION ON YOUR LIST.

CHAIRMAN THOMAS: MR. SHEEHY.

MR. SHEEHY: 5346. I JUST HAD A QUESTION FOR STAFF. SINCE WE HAVE THE EXTRAORDINARY PETITION AND WE'RE DISCUSSING THIS, IS IT POSSIBLE TO GET THE SCORES AND THE HIGHS, LOWS, STANDARD DEVIATION? THAT'S A LITTLE BIT HELPFUL TO GIVE US A FRAMEWORK.

DR. JUELSGAARD: THANK YOU, CHAIRMAN THOMAS. LET ME ASK THE PRESENTER. SO YOU SAID YOU MET WITH THE FDA, AND THE FDA IS A REALLY BIG ORGANIZATION. CAN YOU TELL ME WHAT PARTICULAR BRANCH OF THE FDA YOU MET WITH? AND IN PARTICULAR DID YOU MEET WITH EITHER REPRESENTATIVES OF CDER, THAT IS THE CENTER FOR DRUG EVALUATION AND RESEARCH, OR CBER, THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH? DID YOU MEET WITH REPRESENTATIVES OF EITHER OF THOSE TWO ORGANIZATIONS?

DR. SOO: WE MET WITH REPRESENTATIVES OF CDRH. WE SUBMITTED A WRITTEN PACKET, A PRE-IDE PACKET, AND HAD THEM COMMENT ON WHICH REGULATORY

PATHWAY.

DR. JUELSGAARD: SO THAT ORGANIZATION, BASED ON MY EXPERIENCE WITH THE FDA, DON'T SPEAK FOR EITHER CDER OR CBER. THOSE ORGANIZATIONS SPEAK FOR THEMSELVES. SO WHAT YOU ARE TALKING ABOUT DOING, AND I'M GOING TO CHALLENGE THE NOTION THAT THIS WILL NOT BE SUBJECT TO EITHER AN NDA OR MORE LIKELY A BLA, PARTICULARLY WITH THE NELL-1 PROTEIN. SO THE NELL-1 IS A PROTEIN. IT'S GOING TO BE DELIVERED FROM OUTSIDE THE BODY TO INSIDE THE BODY. IT'S GOING TO HAVE AN ACTIVITY, IF IT WORKS, INSIDE THE BODY. AND IT'S GOING TO BE PRODUCED IN CELL CULTURE. ALL OF THOSE ARE EXACTLY IDENTICAL TO WHAT EXISTING PHARMACEUTICAL PROTEIN PRODUCTS DO TODAY, AND THERE ARE A LARGE NUMBER OF THEM, AND ALL OF THEM ARE SUBJECT TO THE BLA OR NDA PROCESS BOTH FOR APPROVAL OF THE PRODUCT ITSELF, BUT ALSO FOR APPROVAL OF THE PROCESS FOR MAKING THE PRODUCT.

I UNDERSTAND THAT YOU HAVE A GMP-COMPLIANT PROCESS RIGHT NOW. BUT ULTIMATELY THE PROCESS IS GOING TO HAVE TO BE APPROVED BY THE FDA IN THAT IT HAS TO OPERATE WITHIN VERY SMALL TOLERABLE LIMITATIONS SO THAT YOU HAVE ESSENTIALLY, BECAUSE THIS IS ALL BEING PRODUCED IN LIVING ORGANISMS, THE SAME OR RELATIVELY THE SAME PRODUCT BEING PRODUCED

ON AN ONGOING BASIS.

SO I HAVE A FAIR AMOUNT OF SKEPTICISM THAT THIS WILL NOT REQUIRE BOTH APPROVAL ON THE DRUG SIDE AS WELL AS ON THE DEVICE SIDE.

DR. SOO: WELL, I FULLY APPRECIATE YOUR COMMENTS. I THINK WHAT DR. FEIGAL HAD COMMENTED ON HISTORICALLY IS THAT BONE REGENERATION PRODUCTS OR PROTEINS SUCH AS BMP-2 CDRH HAS TAKEN THE LEAD. NOW, THAT'S NOT TO SAY THAT CBER OR CDER MAY NOT COME IN AND CONSULT, BUT THE FACT IS THAT CDRH TAKES THE LEAD. AND THE CLINICAL TRIALS THAT WE HAVE TO UNDERTAKE ARE DIVIDED INTO THE PILOT STUDY AND THE PIVOTAL STUDIES.

AND SO THE POINT I'M MAKING IS NOT THAT CBER OR CDER ARE TOTALLY NOT GOING TO BE INVOLVED. IT'S WHO IS GOING TO BE THE PRIMARY. AND IF YOU LOOK AT BMP-2, THAT IS A PROTEIN PRODUCED IN CHO CELLS. THAT IS A BIOLOGIC. THAT IS REGULATED UNDER -- CDRH TAKES THE PRIMARY, AND THEY UNDERWENT PILOT AND PIVOTAL STUDIES FOR THE ORIGINAL BMP-2 APPROVAL. NOW, EVEN RECENTLY BMP-2 TRIED OR MEDTRONICS TRIED TO HAVE A HIGHER DOSE BMP-2 APPROVED IN THEIR PRODUCT CALLED AMPLIFY. EVEN THAT WAS UNDER CDRH IN TERMS OF THEY HAD PILOT AND PIVOTAL STUDIES. IN THEIR PIVOTAL STUDIES, THEY HAD

LESS THAN 500 PATIENTS. THEY HAD 200 SOMETHING PATIENTS IN EACH ARM, SO THEY STILL WENT THROUGH THE PILOT AND PIVOTAL.

THAT'S THE MAIN POINT I'M MAKING; THAT IS, OUR PATHWAY COULD POTENTIALLY SAVE SIGNIFICANT TIME BECAUSE YOU DO NOT HAVE TO DO THE THREE TYPICAL PHASES.

DR. JUELSGAARD: NO. MY POINT IS, RATHER, THAT THE APPROVAL PROCESS IS NOT SIMPLY A DEVICE APPROVAL PROCESS. IT'S BOTH A DEVICE AND A BIOLOGICS APPROVAL PROCESS. AND PART OF THAT APPROVAL PROCESS WILL BE THE FDA, IN PARTICULAR CBER -- NO, CDER IN THIS CASE, WILL WANT TO BE ASSURED OF THE SAFETY AND EFFICACY OF THE MOLECULE BECAUSE THAT'S THEIR PROVINCE, AS WELL AS ASSURANCES OF THE MEANS OF PRODUCING IT THAT WANT TO APPROVE THAT PRODUCTION PROCESS.

IT WOULD BE INCONCEIVABLE TO ME THAT YOU WOULD ESCAPE THAT PARTICULAR ASPECT OF THE APPROVAL PROCESS. AND THAT'S NOT AN UNTIME-CONSUMING PROCESS.

DR. SOO: YOU ARE EXACTLY RIGHT OF THAT. THE TIME AND COST SAVINGS THAT I'M TALKING ABOUT IS THE TWO-PHASE CLINICAL TRIAL COMPONENT AND THAT YOU DO NOT HAVE TO HAVE THREE-PHASE TRIALS, IN WHICH

CASE YOU WOULD SAVE TIME, SAVE THE NUMBER OF HUMAN SUBJECTS THAT YOU WOULD NEED TO RECRUIT BECAUSE YOU ARE DOING ONE LESS PHASE, AND ALSO THAT WOULD DECREASE OVERALL TIME AND COST.

ANY OTHER QUESTIONS?

CHAIRMAN THOMAS: ANY OTHER COMMENTS BY BOARD MEMBERS?

SO, MR. HARRISON, AT THIS STAGE, HAVING NOW HEARD THE PETITION, WHAT IS THE APPROPRIATE NEXT STEP, IF ANY?

MR. HARRISON: THERE'S NO ADDITIONAL STEP REQUIRED. IF A BOARD MEMBER WOULD LIKE MORE INFORMATION FROM STAFF OR WOULD LIKE TO MAKE A MOTION, THEY'RE FREE TO DO SO. BUT OTHERWISE, YOU CAN MOVE ON TO OTHER APPLICATIONS OF INTEREST TO BOARD MEMBERS OR OTHER QUESTIONS.

DR. PRIETO: WOULD THE MOTION BE TO CONSIDER THE EXTRAORDINARY PETITION?

MR. HARRISON: WELL, NO. TYPICALLY WE WOULD HAVE SOME DISCUSSION, IF THERE IS ANY. IF THERE'S ANY PROPRIETARY INFORMATION YOU'D WANT TO REVIEW, WE'D DO THAT IN CLOSED SESSION, AND THEN A MOTION TO MOVE THE APPLICATION INTO THE FUNDING CATEGORY WOULD OCCUR AFTER A CLOSED SESSION.

MS. LANSING: WE DON'T NEED TO MOVE TO

TALK ABOUT IT.

MR. HARRISON: PRECISELY.

DR. BRYANT: WHAT ABOUT IF WE WANTED TO MOVE THAT IT COULD BE SUBMITTED WITHOUT A PLANNING GRANT? WHERE WOULD THAT MOTION COME FROM?

MR. HARRISON: WE WOULD HAVE TO GIVE THAT A LITTLE BIT OF ADDITIONAL THOUGHT BEFORE RESPONDING SIMPLY BECAUSE IT WAS NOT CONTEMPLATED IN THE RFA.

DR. PRIETO: I WOULD LIKE TO HEAR MORE IN CLOSED SESSION AND KEEP THE POSSIBILITY OF BRINGING IT UP OPEN.

CHAIRMAN THOMAS: I THINK THAT IS THE APPROPRIATE FORUM GIVEN THAT IT WOULD INVOLVE PROPRIETARY INFORMATION. SO I BELIEVE THAT WILL, AS PER DR. PRIETO'S REQUEST, THAT WILL BE THE ORDER HERE. YES, MR. SHEEHY.

MR. SHEEHY: I JUST WANTED TO GET THE SCORES. I JUST THINK IT'S VERY HELPFUL. WE DIDN'T GET THE SCORES FOR GRANTS THAT DIDN'T -- I THINK THAT THAT WILL GIVE US A BETTER SENSE OF WHAT WE'RE WORKING WITH. AS YOU LOOK, IT'S NOT SCORED ON THERE.

DR. SAMBRANO: SO THIS IS APPLICATION 5346, WHICH SITS TWO BELOW THE HIGHEST -- THE LOWEST GREEN ONE, AND THE SCORE IS A 56. THE MEDIAN IS A

60, THE STANDARD DEVIATION IS 13, AND THE RANGE IS BETWEEN 20 AND 70.

AND THEN I'LL JUST REMIND YOU, IN TERMS OF HOW THE TIERS WERE INITIALLY SET UP, THE GREEN LINE ABOVE WHICH THE INITIAL TIER I WAS FORMED WAS AT 71. AND SO MANY OF THOSE OTHERS THAT YOU SEE WITH THE ASTERISK OR CONDITION, THE ASTERISK IS SHOWN ON THE RIGHT-HAND SIDE, THOSE ARE THE FIVE THAT ARE THE LOWEST IN TIER I HAD SPECIAL CONDITIONS ATTACHED. AND SO THIS 5346 SITS AT A SCORE OF 56, TWO BELOW THE LOWEST GREEN.

DR. STEWARD: GIL, MY QUESTION IS ABOUT ACTUALLY THE STAFF REVIEW OF THESE PETITIONS. YOU MENTIONED THAT YOU WERE NOT DOING THAT ANYMORE. I ACTUALLY THOUGHT THAT THAT WAS VERY HELPFUL. JUST CURIOUS.

DR. SAMBRANO: I AGREE. I THINK ONE OF THE CHALLENGES THAT WE FACED IS THAT WHEN WE GET A PETITION ESPECIALLY COMING TWO OR THREE DAYS, AND I'M NOT SUGGESTING THAT THIS ONE DID, BUT OFTEN WHEN WE GOT FLOODED WITH THESE, IT WAS ACTUALLY DIFFICULT TO GIVE AN APPROPRIATE ANALYSIS AND ASSESSMENT. I THINK IN GENERAL WE CAN MAKE AN ASSESSMENT OF WHETHER THE COMMENTS REPRESENT A DIFFERENCE OF OPINION OR IF THERE IS A PARTICULAR POINT THAT MAYBE

YOU SHOULD CONSIDER. SO IN THAT CONTEXT WHAT WE DECIDED TO DO WAS BRING TO YOU THINGS THAT WE THOUGHT WERE OF CONCERN OR ISSUE THAT WE FELT YOU NEEDED TO ADDRESS. AND UNLESS THAT HAPPENS, THAT WE WEREN'T GOING TO NECESSARILY DO A POINT-BY-POINT REBUTTAL TO THE REBUTTAL.

MR. ROTH: JUST ON THAT SAME LINE OF QUESTIONING, I RECALL THAT EXTRAORDINARY PETITIONS WERE FOR SIGNIFICANT FACTUAL ERRORS.

DR. SAMBRANO: NO. THE EXTRAORDINARY PETITION POLICY DOESN'T REALLY DEFINE WHAT AN EXTRAORDINARY CIRCUMSTANCE IS. SO IT'S REALLY THE APPLICANT THAT DETERMINES WHETHER THEY FEEL IT'S AN EXTRAORDINARY CIRCUMSTANCE TO BRING TO THE BOARD.

CHAIRMAN THOMAS: ANY OTHER COMMENTS? OKAY. WE WILL NOW MOVE ON TO THE 19 RECOMMENDED AWARDS. DR. SAMBRANO, DO YOU HAVE SOME PRELIMINARY COMMENTS ON THAT? ARE THERE ANY PARTICULAR AWARDS IN THAT GROUP THAT MEMBERS OF THE BOARD WOULD LIKE TO HEAR SOME MORE INFORMATION ABOUT?

DR. STEWARD: SO IT MIGHT BE USEFUL TO TALK ABOUT 05357 AND WHY IT IS WHERE IT IS AND NOT RECOMMENDED FOR FUNDING BEFORE WE MOVE TO ANYTHING ELSE.

DR. SAMBRANO: DR. SCHEINER.

DR. FEIGAL: I'M JUST GOING TO SAY, AS YOU HAVE QUESTIONS, WE'RE GOING TO HAVE THE SPECIFIC SCIENCE OFFICER WHO'S FAMILIAR WITH THE APPLICATION RESPOND.

DR. SCHEINER: SO, CHAIR THOMAS, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC, I'D BE HAPPY TO PROVIDE A BRIEF INTRODUCTION TO APPLICATION 5357, NEURAL STEM CELL MEDIATED THERAPY FOR PEDIATRIC BRAIN TUMORS, AS WELL AS HIGHLIGHTS FROM THE GRANTS WORKING GROUP REVIEW.

THIS APPLICATION IS FOCUSED ON A NEURAL STEM CELL OR MSC THERAPY FOR CHILDREN WITH SEVERAL TYPES OF MALIGNANT BRAIN TUMORS. THE APPLICANT PROPOSES TO DEVELOP NSC'S THAT ARE GENETICALLY MODIFIED WITH AN ENZYME THAT CONVERTS A SYSTEMATICALLY ADMINISTERED PRO DRUG INTO ITS MORE ACTIVE FORM.

SO YOU MAY HAVE HEARD OF THIS APPROACH BEFORE, SOME OF OUR OTHER FUNDED GRANTS. THE GENERAL IDEA IS THAT THESE TRANSPLANTED NEURAL STEM CELLS WILL MIGRATE TO BRAIN TUMORS WHERE THEY'LL CONVERT A SYSTEMICALLY ADMINISTERED PRO DRUG TO AN ACTIVE DRUG. SO, IN EFFECT, PROVIDING A HIGHLY LOCALIZED DOSE OF CHEMOTHERAPY.

DURING THE RESEARCH AWARD, THE APPLICANT

PROPOSES TO FILE AN IND WITH THE FDA AS WELL AS CONDUCT A PHASE I/II CLINICAL TRIAL WITH TWO ARMS FOR DIFFERENT PATIENT POPULATIONS.

SO IN THE GRANTS WORKING GROUP REVIEW, THE REVIEWERS VIEWED THE MAIN STRENGTHS OF THE APPLICATION AS A SIGNIFICANT UNMET MEDICAL NEED OF PEDIATRIC BRAIN TUMORS AND THE FEASIBILITY OF THE PROJECT. THE KEY WEAKNESSES NOTED BY THE REVIEWERS INCLUDED THE SIMILARITY OF THIS PROJECT WITH AN EXISTING CIRM DISEASE TEAM AWARD, CERTAIN ASPECTS OF THE SCIENTIFIC RATIONALE I'D BE HAPPY TO DISCUSS IF YOU ARE INTERESTED, AND THE APPROPRIATENESS OF ONE OF THE TARGETED TUMOR TYPES, AS WELL AS THE PI'S LACK OF EXPERIENCE LEADING CLINICAL PROGRAMS.

SO THERE WAS A THOROUGH DISCUSSION OF THIS APPLICATION IN PROGRAMMATIC REVIEW. AND DURING THIS DISCUSSION, REVIEWERS SUGGESTED THAT OUTCOMES AND RESULTS FROM THE ONGOING CIRM DISEASE TEAM PROJECT AND A RELATED CLINICAL TRIAL COULD HAVE SIGNIFICANT IMPACT ON THIS PROPOSAL. AND THEY SUGGESTED IT WOULD BE PRUDENT TO WAIT FOR ADDITIONAL DATA GENERATED BY THESE PROJECTS.

SO A MOTION WAS MADE TO MOVE THIS APPLICATION INTO TIER III, NOT RECOMMENDED FOR FUNDING, AND THAT MOTION CARRIED. BE HAPPY TO TAKE

ANY QUESTIONS ABOUT THIS APPLICATION.

DR. STEWARD: THANK YOU VERY MUCH. I WANTED TO RAISE THAT FOR DISCUSSION BECAUSE IT IS A LITTLE BIT UNUSUAL IN THE WAY THE DISCUSSION WENT. IT REALLY IS ONE IN WHICH THERE WAS BOTH AN ISSUE OF ONGOING THINGS THAT WERE VERY SIMILAR AND ALSO THE SUGGESTION THAT IT WOULD BE PRUDENT TO WAIT FOR THE RESULTS OF SOME OF THOSE ONGOING THINGS. I THINK THAT'S SOMETHING THAT THE BOARD SHOULD BE AWARE OF AND PERHAPS DISCUSS AND WEIGH IN ON. THAT'S WHY I WANTED TO RAISE IT.

MR. ROTH: I HAVE A QUESTION ABOUT HOW THE ORIGINAL CUTOFF LINE WAS SET. IT APPEARS TO ME THAT PERHAPS THE FOUR GREEN RECOMMENDED FOR FUNDING WERE CONSIDERED AFTER THE FUNDING LINE WAS SET HERE. IS THAT POSSIBLE?

MR. SHEEHY: WHAT HAPPENED IS THEY DREW THE LINES VERY BROADLY. AND SOMETIMES YOU HAVE THEM THEY DRAW IT TOO NARROWLY AND YOU HAVE TO MOVE STUFF BACK IN. SOMETIME THEY DRAW IT VERY BROADLY AND THEN YOU HAVE TO MOVE EVERYTHING OUT. SO THAT'S WHAT HAPPENED HERE IS IT WAS A VERY -- IF WE GO BACK, AND I DON'T KNOW IF YOU WANT, BUT DR. BERRY DID A NICE JOB OF SHOWING, THE DISTRIBUTION, THEY WENT WAY LOW THIS TIME FOR THEIR CUT. AND IT WAS

LIKE -- SO THAT'S WHY IT LOOKS A LITTLE WEIRD. AGAIN, IT WAS VERY ROBUST. THEY PUT A LOT -- YOU HAVE TO REMEMBER THESE ARE $100,000 AWARDS, AND A LOT OF THESE THINGS ALMOST HAD GO/NO-GO DECISIONS. IN FACT, IF YOU LOOK AT THE PROGRAMMATIC REVIEW, THEY HAD GO/NO-GO DECISIONS BEFORE THEY CAN EVEN SUBMIT THEIR APPLICATION ON SOME OF THESE.

SO THERE'S A CERTAIN THOROUGHNESS OF LOOKING AT ALL THESE.

DR. TROUNSON: IT WOULD BE FAIR JUST TO POINT OUT THAT THEY GOT ASTERISKS IN THE LAST FIVE, SO THERE WERE SOME CONDITIONS THERE. THEY FELT SUPPORTIVE, BUT ONLY WITH SOME CONDITIONS. SO THAT WAS A BIT UNUSUAL. WE HADN'T DONE MUCH OF THAT, VERY OCCASIONAL IN THE PAST, BUT THIS WAS A LITTLE UNUSUAL IN THIS RFA TO HAVE DONE THAT, TO PROVIDE A SORT OF GROUP THAT UNDER SOME CONDITIONS THEY WOULD BE SUPPORTIVE, BUT NOT BROADLY.

DR. SAMBRANO: I HIGHLIGHTED, I'M NOT SURE IF YOU CAN SEE IT, BUT BASICALLY AT ABOUT 71 AND BELOW. AND THEN ABOVE WHAT WAS 51, WHICH IS APPROXIMATELY 5419, THAT WAS THE RANGE THAT WAS BETWEEN TIER III AND TIER I. AND EACH OF THOSE WAS DISCUSSED. AND I THINK THE DISCUSSION WAS SUCH THAT THE RESULT OF MANY WAS EITHER NOT TO RECOMMEND IT,

IN SOME CASES TO PROVIDE A CONDITION UNDER WHICH THE RECOMMENDATION WOULD BE MADE, AND THEN ONE OR TWO MAYBE THAT WERE JUST OUTRIGHT RECOMMENDED.

CHAIRMAN THOMAS: DEAN HAWGOOD.

DR. HAWGOOD: JUST A CLARIFICATION ON THIS ISSUE OF CONDITION. CONDITION THAT THEY NEED TO MEET TO GET THE PLANNING GRANT, OR A CONDITION THAT THEY NEED TO MEET TO SUBMIT THE FULL PROPOSAL?

DR. SAMBRANO: IF YOU APPROVE, IT MEANS THAT THEY THEN GET THE CHOICE OF ACCEPTING THE PLANNING AWARD AND MOVING FORWARD WITH AN APPLICATION FOR THE RESEARCH AWARD. AND THEN AT THE TIME OF THE RESEARCH AWARD APPLICATION, X CONDITION NEEDS TO BE MET.

DR. PIZZO: I JUST WANT TO COME BACK TO THE COMMENT THAT DR. STEWARD MADE BECAUSE I THINK THAT HE WAS RAISING AN IMPORTANT ISSUE, WHICH IS NOT SIMPLY RESTRICTED TO THIS PROPOSAL, BUT TO OTHERS, WHICH IS NOW THAT WE HAVE A PORTFOLIO, SO TO SPEAK, OF DIFFERENT EXPERIMENTS UNDER WAY, WILL WE BEGIN SAYING THAT THERE'S REDUNDANCY AND, THEREFORE, WE SHOULDN'T GO FORWARD? AND MY VIEW ABOUT THAT IS, AND IT COMES BACK TO A COMMENT THE CHAIR MADE EARLIER, IS THAT WE SHOULDN'T NECESSARILY PRECLUDE THINGS BECAUSE OF THAT.

ON THE OTHER HAND, WE SHOULD BE MINDFUL OF OVERINVESTMENT IN ANY AREA AND SHOULD, THEREFORE, HAVE KIND OF A LITMUS TEST OF IS THERE SOMETHING UNIQUE IN THIS NEW PROPOSAL THAT MAY BE USING A SIMILAR METHODOLOGY. IF IT'S VERY SIMILAR TO OTHERS AND WE CAN WAIT, I THINK THEN IT DOESN'T, AT LEAST FROM A HYPOTHETICAL POINT OF VIEW, TO ME AT LEAST, SUGGEST ADDITIONAL INVESTMENT. BUT I WOULDN'T MAKE THIS A POLICY THAT BECAUSE THERE'S A PORTFOLIO, WE SHOULD DO THAT. I THINK THAT'S THE POINT YOU WERE RAISING.

DR. STEWARD: YEAH. ACTUALLY IF YOU DON'T MIND, JUST TO AMPLIFY ON IT BECAUSE I DO THINK THAT THERE'S SORT OF TWO KEY POLICY THINGS. ONE IS EXACTLY THAT, THE PORTFOLIO ISSUE. AND THE OTHER WAS THE COMMENT THAT WE HAVE THIS ONGOING AND SO WE SHOULD WAIT FOR THE RESULTS. AND I'M NOT SURE HOW I FEEL ABOUT THAT. I JUST WANTED TO LAY IT OUT THERE AS ONE OF THE THINGS THAT WAS DISCUSSED AND REALLY PROBABLY ONE OF THE THINGS THAT ENDED UP HAVING THIS GRANT RECOMMENDED FOR NONFUNDING. DO WE REALLY WANT TO DO THAT GOING FORWARD?

I JUST WANTED TO RAISE IT AS THE ISSUES THAT WERE THE KEY THINGS IN PLAY HERE.

DR. PIZZO: JUST BECAUSE I THINK THAT WAS

PART OF THE DIALOGUE THAT YOU AND I ARE HAVING, I HEARD THAT AS WELL. AND I UNDERSTAND THAT. AND I THINK THAT PART OF THE ADMONITION IS THAT IF THERE ARE A SET OF EXPERIMENTS UNDER WAY, AND THIS IS ONE OF A SIMILAR KIND, THERE COULD BE A BENEFIT TO WAIT AND SEE WHETHER THE OTHERS HAVE WORKED. HERE I WOULD SAY IF THE EXPERIMENT'S SIMILAR IN PROFILE, BUT YET BRINGING SOME OTHER UNIQUE ELEMENT TO IT IS SOMETHING THAT WE SEE, THEN I WOULDN'T HAVE THE SAME PROHIBITION. I JUST THINK WE NEED TO BE MINDFUL OF NOT OVERINVESTING IN WHAT MIGHT BE A DEAD END IF THERE'S A LOT OF THINGS THAT ARE GOING ON.

DR. POMEROY: I JUST WANTED TO KIND OF AMPLIFY WHAT DUANE SAID, THAT IN THIS INSTANCE, IT'S NOT THAT THIS WAS REMOVED FROM THE FUNDING RANGE, BUT RATHER THAT IT FELL OUTSIDE THE FUNDING RANGE AND THERE WAS NO COMPELLING REASON TO MOVE IT UP AS OPPOSED TO SOME OF THE OTHERS AROUND IT. SO I THINK IT'S VERY DIFFERENT TO REMOVE SOMETHING FROM THE FUNDING RANGE BECAUSE OF PORTFOLIO CONSIDERATIONS VERSUS THE CONCEPT OF MOVING SOME THINGS UP TO COMPLETE A PORTFOLIO. I THINK THAT'S AN IMPORTANT DISTINCTION, THAT THIS SCORE DID NOT FALL IN THE ORIGINAL RECOMMENDED FOR FUNDING RANGE.

DR. STEWARD: ACTUALLY I'M NOT SURE ABOUT

THAT, AND MAYBE WE SHOULD -- I SORT OF HESITATE TO DO IT, BUT MAYBE WE SHOULD PUT THE SCORE UP AND SEE WHERE IT DID FALL. I DON'T RECALL WHERE THE SCORE WAS.

DR. SAMBRANO: IT DID FALL BELOW THE INITIAL TIER I. SO THAT'S WHAT I WAS TRYING TO SHOW IN THAT LINE UP THERE.

DR. STEWARD: YOU PUT THAT LINE UP THERE.

DR. LOVE: SO, JON, JUST IN RESPONSE TO OS' SPECIFIC QUESTION. I DO THINK IT'S VERY NORMAL IF WE WANT TO MANAGE OUR INVESTMENTS OF THE DOLLARS IN A PORTFOLIO STRATEGY. IT IS VERY NORMAL, I THINK, TO THINK ABOUT OVERLAPPING EXPERIMENTS. AND WHEN EXPERIMENTS HAVE A GREAT DEAL OF OVERLAP, IT DOES, IN FACT, MAKE SOME SENSE TO THINK ABOUT WHETHER OR NOT SEEING THE INFORMATION FROM THE FIRST EXPERIMENT COULD HELP YOU DECIDE IF YOU WANT TO DO THE SECOND EXPERIMENT OR IF YOU WANT TO DO THE SECOND EXPERIMENT IN A DIFFERENT WAY.

AND I GUESS THE ONLY OTHER THING TO POINT OUT IS THAT, AT LEAST IN LOOKING AT THE MATERIALS, THERE WAS AT LEAST ANOTHER MAJOR CONCERN RAISED, THAT I ASSUME IS IN THE PUBLIC MATERIALS, ABOUT THE TEAM INVOLVED AS WELL. SO I THINK THERE WERE TWO ISSUES, BUT I'M CERTAINLY VERY SUPPORTIVE AT LEAST

OF LOOKING AT NOT INVESTING IN THE EXACT SAME REPEAT EXPERIMENTS CERTAINLY BEFORE WE GET THE RESULTS FROM THE FIRST.

CHAIRMAN THOMAS: I WOULD ADD TO THAT THAT IT SOUNDS LIKE $3 BILLION IS A LOT OF MONEY, BUT THERE'S TREMENDOUS AMOUNT OF RESEARCH TO BE FUNDED, AND IT IS A LIMITED RESOURCE, AND WE HAVE TO BE JUDICIOUS ABOUT HOW WE SPEND IT.

DR. FEIGAL: WELL, I ALSO WANTED TO REMIND YOU. THE PLANNING AWARD, ALTHOUGH 3 BILLION, A HUNDRED THOUSAND EACH MAY SOUND SMALL. AS DR. THOMAS SAYS, IT'S IMPORTANT THAT WE SPEND IT WISELY. NOT TO IMPLY WE WOULD NOT. BUT WE'RE ALSO TALKING ABOUT THIS IS THE ENTREE INTO $20 MILLION AWARDS, AND THIS IS JUST THE FIRST PIECE. SO THEY WILL HAVE ENTREE IF YOU FUND THIS OR MAKE THAT DECISION FOR THAT MUCH LARGER PURSE. SO I JUST WANT YOU TO THINK ABOUT THAT IN CONTEXT.

CHAIRMAN THOMAS: OTHER COMMENTS FROM MEMBERS OF THE BOARD ABOUT ANY OF THE EITHER RECOMMENDED OR NOT RECOMMENDED PROJECTS? HEARING NONE, THEN I THINK WE ARE SET TO MOVE TO CLOSED SESSION ON A COUPLE OF TOPICS. I ASK MR. HARRISON TO ADMONISH US ON THOSE TOPICS, PLEASE.

MR. HARRISON: THE BOARD WILL CONVENE IN

CLOSED SESSION TO DISCUSS CONFIDENTIAL INTELLECTUAL PROPERTY OR PROPRIETARY INFORMATION RELATING TO THE DISEASE TEAM THERAPY DEVELOPMENT AWARDS APPLICATIONS PURSUANT TO HEALTH AND SAFETY CODE SECTION 125290.30(F)(3)(B) AND (C) AND ALSO TO DISCUSS PERSONNEL PURSUANT TO HEALTH AND SAFETY CODE SECTION 125290.30(F)(3)(D).

CHAIRMAN THOMAS: THANK YOU. FROM A PRACTICAL STANDPOINT, COULD SOMEBODY DESCRIBE EXACTLY WHERE CLOSED SESSION IS?

MS. KING: RIGHT NEXT DOOR.

CHAIRMAN THOMAS: AND AM I CORRECT THE MEMBERS OF THE BOARD WILL GRAB LUNCH AND TAKE INTO CLOSED SESSION?

MS. KING: YES, THAT IS CORRECT.

CHAIRMAN THOMAS: THANK YOU. SO MEMBERS OF THE PUBLIC, WE ARE TEMPORARILY OUT FOR CLOSED SESSION. THANK YOU.

(THE BOARD THEN WENT INTO CLOSED SESSION, NOT REPORTED NOR HEREIN TRANSCRIBED. THE FOLLOWING WAS THEN HEARD IN OPEN SESSION:)

CHAIRMAN THOMAS: SO WE ARE BACK FROM ADJOURNMENT FROM CLOSED SESSION. IF I COULD HAVE EVERYBODY TAKE THEIR SEAT, PLEASE. MR. HARRISON, DO YOU WANT TO REPORT ON ANYTHING TO BE REPORTED OUT OF

CLOSED SESSION?

MR. HARRISON: I'D LIKE TO REPORT THAT THERE IS NOTHING TO REPORT OUT OF CLOSED SESSION.

CHAIRMAN THOMAS: OKAY. WELL, HAVING HAD THE EXTRAORDINARY PETITION WITH DISCUSSION IN CLOSED SESSION, ARE THERE ANY MEMBERS OF THE BOARD WHICH WOULD LIKE TO MAKE A MOTION WITH RESPECT TO THAT EXTRAORDINARY PETITION? HEARING NONE, WE WILL FILE THAT. THANK YOU FOR THE PRESENTATION OF THE EXTRAORDINARY PETITION. AND IT'S TIME TO MOVE ON TO OUR NEXT AGENDA TOPIC.

DO ANY MEMBERS OF THE BOARD WISH TO MAKE A MOTION TO ELEVATE ANY OF THE TIER III PLANNING AWARDS UP TO TIER I? HEARING NO SUCH MOTION, DO I HEAR A MOTION TO AWARD THE 19 PLANNING AWARDS IDENTIFIED IN THE REPORT PRESENTED?

DR. LOVE: MR. CHAIRMAN, I MOVE THAT WE APPROVE THE GRANTS IN TIER I.

MR. TORRES: SECOND.

CHAIRMAN THOMAS: MR. HARRISON, CONFLICTS PLEASE.

MR. HARRISON: JUST AS A REMINDER, PARTICULARLY FOR THOSE BOARD MEMBERS APPEARING FOR THEIR FIRST TIME, MELISSA WILL CONDUCT A ROLL CALL VOTE. WHEN YOUR NAME IS CALLED, IF YOU HAVE

APPLICATIONS IDENTIFIED ON THE LIST IN FRONT OF YOU WITHIN THE GROUP THAT ARE IN TIER I, YOU SHOULD VOTE EITHER YES OR NO ON THE MOTION EXCEPT AS TO THOSE APPLICATIONS IN WHICH YOU HAVE A CONFLICT.

CHAIRMAN THOMAS: IS THERE ANY PUBLIC COMMENT ON THE TIER I AWARDS?

MS. KING: WE DO HAVE ONE.

CHAIRMAN THOMAS: YES. THANK YOU. WE HAVE TWO MINUTES PER COMMENT.

MS. ROBERSON: THANK YOU SO MUCH. THANK YOU SO MUCH TO CHAIR THOMAS AND DR. TROUNSON AND TO THE ICOC BOARD. WE HAD DR. -- WE ARE HERE ADVOCATING, THE HUNTINGTON'S COMMUNITY IS HERE ADVOCATING FOR DR. JAN NOLTA, HER GRANT FROM UC DAVIS FOR HUNTINGTON'S. SO I WANT TO THANK YOU ALL FOR YOUR HARD WORK.

THIS IS MY DAUGHTER, SHERRY. SHE IS IN THE ANNUAL REPORT, CIRM'S ANNUAL REPORT. AND SHE'S AT RISK FOR HUNTINGTON'S DISEASE ALONG WITH THREE OF MY OTHER CHILDREN AND NOW I HAVE GRANDCHILDREN. MY HUSBAND, HIS BROTHER, HIS MOTHER, HIS GRANDFATHER, AND NOW HIS SISTER HAD HUNTINGTON'S DISEASE. AND WE HAVE 17 MEMBERS IN OUR FAMILY AT RISK FOR HUNTINGTON'S DISEASE.

WE HAVE NO TREATMENTS FOR HUNTINGTON'S

DISEASE AND NO HOPE FOR A CURE OTHER THAN STEM CELL RESEARCH. SO WE'RE GRATEFUL FOR ALL THE WORK THAT YOU'RE DOING HERE AND HAVE BIG HOPE.

I WANT TO SAY THAT AFTER THIS MEETING TODAY, I'LL GO ON MY COMPUTER AND SEND OUT A MASS E-MAIL TO PEOPLE IN THE COUNTRY WHO ARE WATCHING AND WAITING TO SEE WHAT HAPPENED HERE TODAY. 30,000 PEOPLE IN THE U.S. ARE AFFECTED WITH HUNTINGTON'S, AND 150,000 PEOPLE AT MINIMUM ARE AT RISK FOR HUNTINGTON'S DISEASE.

SO, AGAIN, BACK TO SHERRY. SHE JUST GOT ENGAGED AND SHE IS HOPING FOR A LONG AND HAPPY LIFE. AND KNOWING HER, SHE MAKES THE MOST OF EVERY SITUATION. MY OTHER KIDS ARE LIKE THAT TOO. BUT SHE'S AT RISK FOR HUNTINGTON'S. SO MY HUSBAND WAS DIAGNOSED AT 39, DIED AT 51 AT HOME. HE WAS IN A HOSPITAL BED FOR THREE YEARS, AND I WAS ABLE TO TAKE CARE OF HIM BECAUSE I'M A NURSE. BUT MOST PEOPLE AREN'T THAT FORTUNATE, AND THEY DIE IN A NURSING HOME.

SO ANYWAY, THIS IS A BIG HOPE FOR US, AND WE HOPE THAT DR. NOLTA WILL GET HER DISEASE TEAM GRANT. OUR HD COMMUNITY IS ORGANIZED, ENTHUSIASTIC, AND HOPEFUL. AND WE'RE HERE AT ANY TIME TO ADVOCATE FOR CIRM OR FOR ANY RESEARCHER OR PHYSICIANS.

AND I WANT TO SAY ONE THING. I GAVE A TALK IN NOVEMBER OF 2009 IN BALTIMORE, AND AT THE MEETING, IT WAS ON HUNTINGTON'S, WAS DR. CELIA WHITTEN FROM THE FDA, AND SHE'S ON THE COMMITTEE FOR CBER. WHEN I GOT HOME FROM THAT MEETING, I HAD A URGENT PHONE CALL AND E-MAIL SAYING THAT I WAS NOMINATED BY DR. WHITTEN FOR THE FDA.

SO IN MAY OF 2011, JUST A FEW WEEKS AGO, I WAS OFFICIALLY APPOINTED TO THE FDA AS THE FIRST VOTING, THAT'S KIND OF A BIG DEAL, FIRST VOTING PATIENT REPRESENTATIVE FOR HUNTINGTON'S SO I CAN VOTE ON ANY DRUG, DEVICE, OR A BIOLOGIC FOR HUNTINGTON'S.

(APPLAUSE.)

MS. ROBERSON: SO I'M VERY PROUD OF THAT AND EAGER TO TRY TO MAKE A DIFFERENCE. AND TO ALL OF YOU HERE, THANK YOU SO MUCH. I KNOW YOU WORK REALLY HARD AND THAT YOU CARE ABOUT PEOPLE LIKE MY FAMILY WHO'S SUFFERING WITH HUNTINGTON'S DISEASE. THANK YOU.

(APPLAUSE.)

MR. KRULL: JUST REAL QUICK. WE WANTED TO SAY THANK YOU ALSO. I THINK WE'VE SPOKE TO YOU BEFORE. OUR DAUGHTER EMILY WHO IS ADOPTED HAD JUVENILE HUNTINGTON'S DISEASE. SHE PASSED AWAY WHEN

SHE WAS 21. BEFORE THAT SHE WAS DIAGNOSED WHEN SHE WAS IN HIGH SCHOOL. SHE LOVED BASKETBALL, SOCCER, FISHING, CAMPING, READING, JUST EVERYTHING KIDS DO, AND THEN STARTED GOING DOWNHILL. WE WERE UNAWARE OF WHAT IT WAS AT THE TIME. FIRST TIME -- WE DIDN'T KNOW WHAT HUNTINGTON'S WAS. BUT IT WAS -- WE KEPT GOING. WE DID EVERYTHING WE COULD. WE ENJOYED LIFE WITH HER, TOOK HER EVERYWHERE. WHATEVER SHE WANTED TO DO WE DID IT. WE ENJOYED LIFE. AND WE KEPT GOING BECAUSE OF THE HOPE WE HAD, AND A LOT OF THAT WE GOT FROM YOU GUYS, SEEING WHAT YOU ARE DOING. WHAT YOU ARE DOING IS IMPORTANT AND WE REALLY APPRECIATE IT.

MS. KRULL: WE NEVER TREATED HER LIKE SHE HAD A DISEASE. WE LIVED LIFE TO THE FULLEST BECAUSE IT'S ALL WE CAN DO.

MR. KRULL: THANK YOU. WE APPRECIATE IT.

MS. KRULL: THANK YOU.

(APPLAUSE.)

CHAIRMAN THOMAS: THANK YOU VERY MUCH FOR YOUR COMMENTS. AS WE'VE SAID, WE'RE DOING EVERYTHING WE POSSIBLY CAN TO HELP FIND A CURE FOR THAT AND ALL THE OTHER HORRIBLE DISEASES OUT THERE. SO THANK YOU VERY MUCH FOR COMING TO SHARE YOUR STORY.

DEAN POMEROY.

DR. POMEROY: I THINK WE'VE JUST HEARD FROM MEMBERS OF THE HUNTINGTON'S COMMUNITY, AND I WOULD LIKE TO JUST SAY HOW EFFECTIVE AND HOW IMPACTFUL THEY ARE AS MEMBERS OF OUR TEAM IN FIGHTING THESE DISEASES. AND JUDY'S DAUGHTER ACTUALLY WORKS IN THE LABORATORY TO FIND THE STEM CELL ANSWERS TO THIS. AND I THINK THAT IT'S SORT OF THE EPITOME OF A PARTNERSHIP BETWEEN ACADEMIA AND RESEARCHERS AND THE PATIENT ADVOCATES. AND SO I WANT TO THANK THE WHOLE HUNTINGTON'S COMMUNITY FOR WORKING ON THIS WITH US.

CHAIRMAN THOMAS: THANK YOU. IS THERE ANY FURTHER DISCUSSION ON THE MOTION AMONGST BOARD MEMBERS?

WOULD LIKE TO NOTE THAT WITH RESPECT TO THE MOTION, AS WE HEARD IN PREVIOUS DISCUSSION, FIVE OF THE PROPOSED AWARDS DO HAVE CONDITIONS THAT NEED TO BE MET IN ORDER FOR THEM TO BE ABLE TO PROCEED TO THE ACTUAL APPLICATION PROCESS FOR FULL AWARD.

HAVING NO FURTHER DISCUSSION, MELISSA, PLEASE TAKE A ROLL CALL VOTE.

MS. KING: I THINK JAMES ALREADY WENT OVER THIS, BUT YOUR RESPONSE TO THIS, TO ME CALLING YOUR NAME DURING THIS ROLL CALL, SHOULD BE WHATEVER YOUR

VOTE IS, YES OR NO, WITH THE EXCEPTION OF THE APPLICATIONS WITH WHICH YOU HAVE A CONFLICT OR SOMETHING ALONG THOSE LINES. I LIKE THE VARIATION, SO DON'T COPY ME.

MS. KING: GARY FIRESTEIN.

DR. FIRESTEIN: YES, WITH THE EXCEPTION OF THOSE APPLICATIONS FOR WHICH I HAVE A POTENTIAL CONFLICT.

MS. KING: SUSAN BRYANT.

DR. BRYANT: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: MARCY FEIT.

MS. FEIT: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: LEEZA GIBBONS.

MS. GIBBONS: YES.

MS. KING: MICHAEL GOLDBERG.

MR. GOLDBERG: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: SAM HAWGOOD.

DR. HAWGOOD: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: STEPHEN JUELSGAARD.

DR. JUELSGAARD: YES.

MS. KING: SHERRY LANSING.

MS. LANSING: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: TED LOVE.

DR. LOVE: YES.

MS. KING: BERTRAM LUBIN.

DR. LUBIN: YES.

MS. KING: LEON FINE.

DR. FINE: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: PHIL PIZZO. CLAIRE POMEROY.

DR. POMEROY: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: FRANCISCO PRIETO.

DR. PRIETO: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: ELIZABETH FINI.

DR. FINI: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: ROBERT QUINT.

DR. QUINT: YES, AND I HAVE NO CONFLICTS.

MS. KING: DUANE ROTH.

MR. ROTH: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: JOAN SAMUELSON.

MS. SAMUELSON: YES.

MS. KING: JEFF SHEEHY.

MR. SHEEHY: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: JON THOMAS.

CHAIRMAN THOMAS: YES.

MS. KING: OSWALD STEWARD.

DR. STEWARD: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: ART TORRES.

MR. TORRES: AYE.

MS. KING: KRISTINA VUORI.

DR. VUORI: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: JAMES ECONOMOU.

DR. ECONOMOU: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: THANK YOU. FOR THE RECORD THAT MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU VERY MUCH. DO I HAVE A MOTION THAT WE APPROVE NOT TO FUND THOSE PROJECTS LISTED IN TIER III?

DR. LOVE: SO MOVED, THAT WE NOT FUND THE GRANTS IN TIER III.

CHAIRMAN THOMAS: DO I HEAR A SECOND?

DR. JUELSGAARD: SECOND.

CHAIRMAN THOMAS: IS THERE ANY BOARD DISCUSSION? ANY PUBLIC COMMENT? HEARING NONE, MELISSA, PLEASE CALL THE ROLL.

MS. KING: SAME REQUIREMENTS FOR YOUR RESPONSE, PLEASE.

DR. FIRESTEIN: I'M CONFUSED NOW. IF I SAY YES, DOES THAT MEAN NO?

MS. KING: THAT'S CORRECT. IF YOU SAY YES TO THE MOTION --

DR. FIRESTEIN: YES, I APPROVE THE MOTION WITH THE EXCEPTION OF THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: GARY FIRESTEIN.

DR. FIRESTEIN: YES, WITH THE EXCEPTION OF THOSE APPLICATIONS FOR WHICH I HAVE A POTENTIAL CONFLICT.

MS. KING: SUSAN BRYANT.

DR. BRYANT: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: MARCY FEIT.

MS. FEIT: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: LEEZA GIBBONS.

MS. GIBBONS: YES.

MS. KING: MICHAEL GOLDBERG.

MR. GOLDBERG: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: SAM HAWGOOD.

DR. HAWGOOD: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: STEPHEN JUELSGAARD.

DR. JUELSGAARD: YES.

MS. KING: SHERRY LANSING.

MS. LANSING: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: TED LOVE.

DR. LOVE: YES.

MS. KING: BERTRAM LUBIN.

DR. LUBIN: YES.

MS. KING: LEON FINE.

DR. FINE: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: CLAIRE POMEROY.

DR. POMEROY: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: FRANCISCO PRIETO.

DR. PRIETO: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: ELIZABETH FINI.

DR. FINI: YES, EXCEPT FOR THOSE WITH

WHICH I HAVE A CONFLICT.

MS. KING: ROBERT QUINT.

DR. QUINT: YES. I HAVE NO CONFLICTS.

MS. KING: DUANE ROTH.

MR. ROTH: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: JOAN SAMUELSON.

MS. SAMUELSON: YES.

MS. KING: JEFF SHEEHY.

MR. SHEEHY: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: JON THOMAS.

CHAIRMAN THOMAS: YES.

MS. KING: OSWALD STEWARD.

DR. STEWARD: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: ART TORRES.

MR. TORRES: AYE.

MS. KING: KRISTINA VUORI.

DR. VUORI: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: JAMES ECONOMOU.

DR. ECONOMOU: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: THANK YOU. FOR THE RECORD THAT

MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU VERY MUCH. WE'RE GOING TO JUST DISPENSE WITH A TWO-SECOND ITEM, AND WE'RE GOING TO TAKE ONE ITEM OUT OF ORDER. WE'RE GOING TO ITEM 9, WHICH IS THE MINUTES OF THE PREVIOUS MEETING.

MS. LANSING: SO MOVED.

MR. TORRES: SECOND.

CHAIRMAN THOMAS: IT'S BEEN MOVED AND SECONDED. ANY DISCUSSION? MOVED TO APPROVE. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? MOTION CARRIES.

NOW, WE HAVE A VERY SPECIAL AGENDA ITEM, WHICH IS ITEM 15, WHICH DUE TO THE FACT WE ARE HAVING SHERRY PROMINENTLY FEATURED IN THIS ITEM, AND SHE'S GOING TO HAVE TO LEAVE, WE ARE GOING TO NOW PROCEED TO A RESOLUTION AND FURTHER COMMENT EXTOLLING THE EXCEPTIONAL CONTRIBUTIONS AND VIRTUE OF MELISSA.

SO, SHERRY, IF YOU WOULD LIKE TO TAKE THE FLOOR. AND WHEN SHERRY IS FINISHED, I HAVE AN ADDITIONAL LITTLE ITEM THAT I WOULD LIKE TO CONVEY AS WELL.

MS. LANSING: MELISSA, THIS IS A BITTERSWEET THING FOR ME TO DO, AND I THINK I SPEAK

FOR ALL OF US IN THE BOARD. WE HAVE WORKED WITH YOU, SOME OF US, FOR CLOSE TO SEVEN YEARS. AND AS I SPEAK FOR ALL THE MEMBERS OF THE BOARD, I FIND THAT WORDS ARE REALLY TRULY INADEQUATE TO EXPRESS OUR EXTREME GRATITUDE FOR EVERYTHING THAT YOU'VE DONE FOR US AND FOR THE MISSION OF STEM CELL RESEARCH.

YOU HAVE BEEN SUCH AN INCREDIBLE SOURCE FOR THIS BOARD. FIRST OF ALL, YOU'VE ORGANIZED US IN EVERY POSSIBLE WAY, WHETHER IT'S JUST GETTING US THE MATERIALS, WHETHER IT'S ORGANIZING WHERE WE'RE GOING TO HAVE LUNCH, WHETHER IT'S ORGANIZING WHETHER THE ROOM IS TOO HOT OR TOO COLD. FROM EVERYTHING THAT WAS MAJOR TO MINOR, YOU HAVE BEEN A SOURCE OF ORGANIZATION.

BUT FAR MORE IMPORTANT TO THAT, I THINK I SPEAK FOR ALL OF US WHEN I SAY YOU HAVE BEEN AN INCREDIBLE SOURCE OF KNOWLEDGE. I CALL YOU CONSTANTLY. AND WHEN I THINK HOW MANY TIMES I CALL YOU AND ASK YOU TO EXPLAIN THINGS FOR ME, AND WHEN I DOUBLE IT BY THE NUMBER OF TIMES ALL OF THE BOARD MEMBERS DO, I DON'T KNOW HOW YOU RETAIN THE INCREDIBLE KNOWLEDGE THAT YOU HAVE. BUT I ALSO DON'T KNOW HOW YOU RETAIN THE INCREDIBLE CALMNESS OF YOUR DEMEANOR. YOU ARE ALWAYS CALM NO MATTER WHAT'S GOING ON, NO MATTER WHAT CRISIS WE'RE FACING, AND

YOU'RE ALSO ALWAYS CHEERFUL. YOU HAVE A SMILE AND A WAY ABOUT YOU THAT CALMS ALL OF US AND MAKES US FEEL BETTER AND REMINDS US OF WHY WE'RE ALL DOING WHAT WE'RE DOING.

IN MANY WAYS YOU'RE THE CONSCIENCE OF THIS ORGANIZATION. IN MANY WAYS YOU'RE THE SOUL OF THIS ORGANIZATION. AND THE REASON THAT YOU'RE ABLE TO DO THIS, MELISSA, IS BECAUSE YOU CARE SO MUCH. WHEN I THINK ABOUT WHEN WE ALL STARTED FROM THE VERY BEGINNING, I THINK ABOUT HOW DEDICATED YOU ARE AND HOW MUCH YOU CARE FOR OUR MISSION AND FOR EVERY PATIENT THAT HAS COME FORWARD TO ALL OF US DURING THESE TIMES AND FOR ALL OF THE PATIENT ADVOCATES HOW MUCH YOU CARE FOR US AND FOR ALL THE SCIENTISTS AND ALL OF THE STAFF AND ALL OF THE ADMINISTRATION.

I SIMPLY CANNOT IMAGINE CIRM WITHOUT YOU, MELISSA. BUT I WOULD BE VERY SELFISH, AND I'D LIKE TO BE VERY SELFISH AND SAY PLEASE DON'T LEAVE, BUT I WOULD BE VERY SELFISH IF I DIDN'T SAY TO YOU THAT I WISH YOU BEST OF LUCK IN YOUR NEW VENTURE AT THIS WONDERFUL INSTITUTION THAT DR. PIZZO SO REMINDED ME OF. I KNOW THAT YOU WILL SUCCEED IN ANYTHING THAT YOU SET YOUR MIND TO. BUT I ALWAYS WANT YOU TO KNOW THAT YOU WILL BE IN THE HEART OF EVERY SINGLE ONE OF US. AND WHENEVER WE THINK ABOUT WHAT WE'RE GOING TO

DO NEXT, I'M ALWAYS GOING TO SAY WHAT WOULD MELISSA DO. SO IT IS IN THAT SPIRIT THAT I THANK YOU ON BEHALF OF ALL OF US FOR EVERYTHING THAT YOU'VE DONE FOR US AND PRESENT YOU WITH THIS RESOLUTION OF GRATITUDE, WHICH I'M NOT GOING TO READ BECAUSE IT'S VERY LONG, BUT IT'S SIGNED BY ALL OF US, AND JUST TELL YOU WE REALLY LOVE YOU AND MISS YOU ALREADY.

(STANDING OVATION.)

CHAIRMAN THOMAS: SO I HAVE A LITTLE ADDITIONAL ITEM I WOULD LIKE TO GIVE TO MELISSA AS A TOKEN OF EVERYBODY'S APPRECIATION. IT'S SORT OF SPECIFIC TO ME, BUT HOPEFULLY IT WILL BE MEANINGFUL TO MELISSA.

SO AS YOU KNOW, I'M FROM LOS ANGELES. I AM A HUGE LOS ANGELES SPORTS FAN. IT'S ONE OF THE -- IT'S TWO OF THE GREAT IRONIES OF ASSUMING THIS POSITION THAT, NO. 1, MY OFFICE WINDOW LOOKS OUT ON AT&T PARK, AND I HAVE TO LOOK AT WILLIE MAYS EVERY DAY. THAT'S BAD ENOUGH.

NO. 2, EVEN WORSE, I COME INTO THIS NEW JOB AND THE PERSON OF EXTREME IMPORTANCE TO THE BOARD IS A BOSTON CELTICS FAN. I CANNOT TELL YOU HOW MUCH I HATE THE CELTICS, BUT I DIGRESS.

SO I WANTED TO GET SOMETHING FOR MELISSA THAT HITS ON THIS THEME AS MUCH AS I DISLIKE IT, BUT

I KNEW SHE WOULD LIKE IT. I WAS RECENTLY BACK WITH MY 12-YEAR-OLD SON AT AN ALL STAR BASEBALL TOURNAMENT IN COOPERSTOWN, NEW YORK. AND COOPERSTOWN, FOR THOSE OF YOU WHO HAVEN'T BEEN, IS A CHARMING LITTLE TOWN, THE MAIN STREET OF WHICH IS ABOUT FOUR BLOCKS LONG, AND IT'S 100 PERCENT MEMORABILIA. AND 99.9 PERCENT OF THAT IS BASEBALL.

ON THE OTHER HAND, THERE IS A POINT 1. SO WHEN I WAS BACK THERE, I SAID I HAVE A COLLEAGUE THAT IS ABOUT TO BE LEAVING TO GO TO BUSINESS SCHOOL WHO IS A CELTICS FAN. DO YOU HAVE ANY GOOD, UNUSUAL, AND UNIQUE CELTICS MEMORABILIA? WELL, TURNS OUT THAT THIS PERSON DID.

A NUMBER OF YEARS AGO THE BASKETBALL HALL OF FAME, WHICH IS IN SPRINGFIELD, MASS., COMMISSIONED AN ARTIST TO MAKE METALLIC BASKETBALL CARDS OF DIFFERENT WORTHY PLAYERS AND PEOPLE WHO PLAYED FOR THE CELTICS.

AND TO MELISSA I WOULD LIKE TO PRESENT A BOOK. MELISSA, IF YOU WOULD STAND UP HERE, PLEASE. WHICH FRONT PAGE OF WHICH SAYS METAL SPORTS CARDS, CARDS FEATURING THE LEGENDARY HALL OF FAMERS OF THE CELTICS. AND IF WE FLIP THROUGH HERE, WE SEE LARRY BIRD, DAVE COWANS FOR THOSE OF YOU CELTICS FANS FROM THE '70S, JOHN HAVLICEK.

MS. KING: EVERYONE KNOWS HAVLICEK.

CHAIRMAN THOMAS: TOM HEINSOHN, THE MOST BIASED SPORTS ANALYST EVER. KEVIN "CLOTHESLINE" MCHALE, AND MY LEAST ALL-TIME FAVORITE ARNOLD "RED" AUERBACH.

WE HAVE THESE CARDS TOGETHER WITH THE CERTIFICATION OF AUTHENTICITY AS A COMMISSIONED METAL SPORTS CARD FROM THE NBA HALL OF FAME. AND IT IS WITH GREAT PLEASURE THAT I PRESENT THESE TO A TRUE CELTICS FAN WITH BEST WISHES GOING FORWARD. HERE YOU GO, MELISSA.

MS. KING: THANK YOU SO MUCH.

(APPLAUSE.)

MR. TORRES: MR. CHAIRMAN, THE DELEGATE FROM THIS CORNER MOVES TO ADOPT THE RESOLUTION.

MS. LANSING: SECOND.

CHAIRMAN THOMAS: WHO WOULD LIKE TO COMMENT ON THE RESOLUTION? I THINK WE ALL DID WITH OUR STANDING OVATION. I MOVE THE QUESTION. ALL THOSE RESOUNDINGLY IN FAVOR SAY -- OH, PUBLIC COMMENT. SORRY. SORRY, DON. HOW COULD I DO THAT?

MR. REED: SOME THINGS MUST BE THOROUGHLY DISCUSSED.

WHENEVER I HEAR THE PLEDGE OF ALLEGIANCE THE REST OF MY LIFE, I'LL THINK OF IT AS AN

INCLUSION. IT SAYS STAND IF YOU ARE ABLE. MY SON COMES IN HERE IN HIS WHEELCHAIR, AND HE ALWAYS FEELS MELISSA IS SPEAKING DIRECTLY TO HIM. AND SHE SPEAKS TO EVERY ADVOCATE. SHE IS THE ADVOCATE'S ADVOCATE. WE WILL NEVER SAY GOODBYE. THANK YOU.

(APPLAUSE.)

CHAIRMAN THOMAS: ANY FURTHER PUBLIC COMMENT? HEARING NONE, ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? UNANIMOUSLY CARRIED.

(APPLAUSE.)

CHAIRMAN THOMAS: ON TO ITEM NO. 10, CONSIDERATION OF FINAL ADOPTION OF AMENDMENTS TO REGULATION 10080 ENTITLED "ACCEPTABLE RESEARCH MATERIALS." DR. LOMAX.

DR. LOMAX: THANK YOU, MR. CHAIRMAN, MEMBERS OF THE BOARD. AS YOU MAY BE AWARE, THE CIRM REGULATIONS REQUIRE HUMAN EMBRYONIC STEM CELL LINES USED BY OUR RESEARCHERS TO MEET STANDARDS FOR THEIR ETHICAL DERIVATION. TO FACILITATE ACCESS TO ETHICALLY DERIVED STEM CELL LINES, OUR REGULATIONS ENUMERATE SPECIFIC REGULATORY FRAMEWORKS THAT CONFORM TO OUR STANDARDS. SO THE FRAMEWORKS REQUIRE EVERYTHING IN THE DERIVATION PROCESS THAT WE WOULD REQUIRE IN OUR OWN STANDARDS.

ONE SUCH FRAMEWORK IS THE AUSTRALIAN

RESEARCH GUIDELINES. IT'S AN ACT WITHIN THE AUSTRALIAN LAW WHICH WAS REVIEWED BY THE STANDARDS WORKING GROUP.

ON THE 8TH OF DECEMBER LAST YEAR, THE STANDARDS WORKING GROUP BROUGHT FORWARD FOR YOUR CONSIDERATION A RECOMMENDATION TO INCLUDE THOSE STANDARDS AS PART OF OUR REGULATIONS. YOU APPROVED THEM THAT TIME, AND WE ENTERED THE RULEMAKING PROCESS. WE RECEIVED NO PUBLIC COMMENTS ON THE PROPOSED REGULATION. WE'RE COMING BACK TO YOU AT THIS TIME TO RECOMMEND FINAL APPROVAL FOR THAT REGULATION.

MR. SHEEHY, DID YOU HAVE A QUESTION?

MR. SHEEHY: NO. OUR ADVOCATES ARE LEAVING. I'M JUST WAVING BYE.

DR. LOMAX: SO THE MOTION BEFORE YOU WOULD BE TO APPROVE THE FINAL LANGUAGE, WHICH IS INCLUDED IN YOUR PACKET, WHICH WOULD ALLOW OUR REGULATIONS TO BE FINALIZED TO INCLUDE THE AUSTRALIAN FRAMEWORK AS ACCEPTABLY DERIVED IN OUR REGULATORY STANDARDS.

DR. PRIETO: DOES THIS REQUIRE A MOTION? I'LL SO MOVE.

DR. LOVE: SECOND.

CHAIRMAN THOMAS: IT'S BEEN MOVED AND SECONDED. IS THERE ANY BOARD DISCUSSION ON THIS

TOPIC? ANY PUBLIC COMMENT ON THIS TOPIC? HEARING NONE, MELISSA, DOES THIS JUST REQUIRE AN AYE VOTE?

ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? MOTION CARRIES.

DR. LOMAX: THANK YOU, MR. CHAIRMAN.

CHAIRMAN THOMAS: THANK YOU, DR. LOMAX.

AGENDA ITEM NO. 11, CONSIDERATION OF PROCESS FOR OBTAINING SUPPLEMENTAL INFORMATION FROM APPLICANTS FOR DISEASE TEAM AND CLINICAL TRIAL AWARDS. DR. FEIGAL.

DR. FEIGAL: SO ONCE AGAIN, YOU'VE SEEN THIS CHEVRON BEFORE. IT'S JUST SHOWING YOU THAT OUR DISEASE TEAM AND TARGETED CLINICAL DEVELOPMENT AWARDS ARE CIRM'S KEY INITIATIVES TO MOVE RESEARCH TOWARDS AND INTO THE CLINIC. RESEARCH, AS WE KNOW, REQUIRES MULTIDISCIPLINARY EXPERTS FOR EXECUTION AND MULTIDISCIPLINARY EXPERTS TO REVIEW.

SO WE WANTED TO ASK OURSELVES -- THE SYSTEM IS WORKING. THE REVIEW PROCESS IS WORKING. BUT HOW CAN WE IMPROVE UPON AN ALREADY STRONG FOUNDATION OF REVIEW BY THE GRANTS WORKING GROUP AND DECISIONS BY THE ICOC? AND SO WE WANTED TO ADDRESS THE ISSUE IN REAL TIME OF CRITICAL QUESTIONS AND ISSUES THAT COULD IMPACT ON REVIEW OF AN APPLICATION, PARTICULARLY THE COMPLEXITIES OF AN

APPLICATION THAT ARE INVOLVED WITH MOVING TOWARDS AND INTO THE CLINIC.

AND WE ALSO WANTED TO DO THIS IN A WAY THAT IT WOULD NOT CHANGE THE CURRENT ROLES OF SCIENTIFIC PEER REVIEW AND PROGRAMMATIC DISCUSSION. SO WE'RE PROPOSING A THREE-PRONG MODIFICATION IN THE CURRENT PROCESS, TWO OF WHICH WE ALREADY HAVE AND HAVE USED IN THE PAST ON AN INFREQUENT BASIS, AND WE'D ACTUALLY LIKE TO FORMALIZE ALL THREE.

THE FIRST IS AT THE TIME OF RFA SOLICITATION AND PRIOR TO APPLICATION RECEIPT. THE SECOND MODIFICATION WILL OCCUR AT THE TIME AFTER CIRM RECEIVES AN APPLICATION AND IT'S SENT TO REVIEWERS. AND THE THIRD TIME WILL BE DURING THE GRANT REVIEW GROUP REVIEW SESSION.

LET ME TELL YOU WHAT THOSE MODIFICATIONS ARE. I WAS JUST POINTING OUT THE TIME POINTS AT WHICH THEY WOULD OCCUR.

PRIOR TO APPLICATION RECEIPT, BUT AFTER THE RFA IS PUBLIC, WE'RE SUGGESTING THAT CIRM HOLD A QUESTION-AND-ANSWER SESSION WITH POTENTIAL APPLICANTS, INCLUDING GOING OVER ISSUES ABOUT THE PROCESS AND ANY OTHER QUESTIONS THE APPLICANTS MAY HAVE. THE POINT IS THAT WE POST THINGS ON OUR WEBSITE. WE USUALLY HAVE PEOPLE SIGN UP FOR

NEWSLETTERS OR ANY TIME WE HAVE A NEW INITIATIVE. THIS WOULD JUST INVOLVE BEING A LITTLE BIT MORE AGGRESSIVE AND ASSERTIVE IN TERMS OF GOING OUT AND ENTERTAINING QUESTIONS AND TRYING TO ADDRESS THEM BEFORE THE APPLICANTS ACTUALLY EVEN START PUTTING TOGETHER THEIR APPLICATION.

SO WE'RE SUGGESTING DOING THIS, AND DOING A WEBINAR OR SOME SORT OF A PUBLIC SESSION, PROBABLY A WEBINAR RATHER THAN A TELECON, IN WHICH WE'D EXPLAIN IT. AND THEN FOR THOSE WHO AREN'T ABLE TO ATTEND THAT, WE'D POST OUR FAQ'S ON THE WEBSITE.

THE SECOND MODIFICATION WOULD BE AFTER THE APPLICATION HAS BEEN RECEIVED, BUT THE APPLICATION IS BEING REVIEWED, IN THE PROCESS OF REVIEW BY THE GRANTS REVIEW GROUP, AND IT WOULD BE BEFORE THE ACTUAL SESSION. AT THIS POINT WE WANTED THE GRANTS REVIEW GROUP TO DO THEIR INITIAL REVIEW AND SEND IN ANY KEY QUESTIONS THAT THEY HAVE ABOUT THE APPLICATION THAT THEY THINK THE APPLICANTS COULD ADDRESS AND GET INFORMATION BACK TO THEM BEFORE THE TIME OF THE ACTUAL SESSION. AND THIS WOULD BE CRITICAL GAPS IN INFORMATION OR CRITICAL AMBIGUITIES IN THE APPLICATION THAT AFFECTED THEIR ABILITY TO REVIEW IT.

CIRM WOULD THEN SEND THESE KEY QUESTIONS

PLUS ANY ADDITIONAL KEY QUESTIONS THE SCIENTIFIC OFFICERS MIGHT HAVE TO THE APPLICANT AND GIVE THEM AN OPPORTUNITY TO ADDRESS THEM. AND THEN THOSE KEY QUESTIONS AND HOW THEY ADDRESS THEM WOULD THEN BE CIRCULATED TO THE GRANTS REVIEW GROUP IN ADVANCE OF THE ACTUAL SESSION.

THE THIRD MODIFICATION WOULD OCCUR DURING THE ACTUAL GRANTS REVIEW GROUP SESSION. THIS IS THE MODIFICATION THAT WE ACTUALLY HAVE NEVER IMPLEMENTED. THIS IS WHERE THE GRANTS REVIEW GROUP MAY HAVE PIVOTAL QUESTIONS THAT ARISE DURING THE ACTUAL DISCUSSION AT THE SESSION. AND IT MAY BE PIVOTAL QUESTIONS OF TWO TYPES. AND THESE WOULD BE QUESTIONS THAT WOULD IMPACT ON THEIR SCORING AND ON THEIR RECOMMENDATION.

ONE TYPE OF QUESTION MAY BE THE TYPE FOR WHICH THERE COULD BE A CONCISE ANSWER AND WE DON'T NEED TO SEE ADDITIONAL WRITTEN INFORMATION, ADDITIONAL DATA. THE SECOND TYPE OF QUESTION COULD BE THAT THAT REQUIRES A MORE COMPLEX EXPLANATION AND WOULD REQUIRE THE SUBMISSION OF ADDITIONAL SUPPLEMENTAL WRITTEN INFORMATION.

THE SCIENTIFIC REVIEW CHAIR OF THAT GRANTS WORKING GROUP WOULD DECIDE DURING THAT SESSION WHETHER PIVOTAL QUESTIONS SHOULD BE COMMUNICATED

WITH APPLICANTS AND OF WHICH TYPE. CIRM THEN WOULD HAVE IDENTIFIED BEFORE THAT ACTUAL SESSION THE CONTACT INFORMATION, JUST THE LOGISTICAL INFORMATION, SO THAT WE'D HAVE THE ABILITY TO CONTACT THEM DURING THE SESSION IN WHICH WE MIGHT WANT TO QUESTION THEM.

SO IF THOSE QUESTIONS DO ARISE AND THE SCIENTIFIC REVIEW CHAIR DECIDES THAT THEY WANT TO POSE THOSE QUESTIONS TO THE APPLICANT, CIRM WOULD THEN PHONE THE APPLICANT DURING THE GRANTS REVIEW GROUP SESSION, AND THERE WOULD BE A TELECON WITH THE GWG IN WHICH THE QUESTIONS WOULD BE STATED TO THE APPLICANT, AND THEY COULD DECIDE WHOMEVER ELSE ON THEIR RESEARCH TEAM THEY WANTED TO BE INVOLVED, WOULD RESPOND IN THE TELECON WITH THE GRANTS REVIEW GROUP. THERE WOULD BE NO DIRECT INTERACTION BETWEEN THE GRANTS REVIEW GROUP AND THE APPLICANT DURING THE PROCESS.

NOW, WE REALIZE IN THE REAL WORLD IT MAY NOT ALWAYS WORK THIS WAY, AND SO WE WANTED TO ENTERTAIN A BACKUP OPTION, IF REAL-TIME TELECON WAS NOT FEASIBLE, TO DO IT BY E-MAIL. SO THE GRANTS REVIEW GROUP WOULD PROVIDE A CONDITIONAL FUNDING RECOMMENDATION BASED UPON RECEIPT OF THE DESIRED RESPONSE FROM THE APPLICANT, WHICH THEN SOME DEFINED

IN RAPID TIME FRAME, THE E-MAIL RESPONSE WOULD THEN BE PROVIDED TO THE GRANTS REVIEW GROUP, BUT IT WOULD NOT REQUIRE FURTHER DISCUSSION. AND THIS QUERY TO THE APPLICANT AND THEIR ANSWER WOULD BE PROVIDED TO THE ICOC TO PROVIDE THEM WITH A BETTER UNDERSTANDING WHEN IT CAME TIME FOR THEM TO MAKE A FINAL DECISION ABOUT THAT APPLICATION.

WHAT ABOUT THE TYPE OF QUESTIONS THAT WOULD REQUIRE THE SUBMISSION OF DATA? HERE THE GRANTS REVIEW GROUP WOULD DEFER FURTHER CONSIDERATION OF THE APPLICATION PENDING RECEIPT OF WRITTEN RESPONSES. THE GRANTS REVIEW GROUP AND CIRM WOULD HAVE TO WORK TOGETHER TO FORMULATE WHAT THOSE PIVOTAL QUESTIONS WOULD LOOK LIKE, THE PERMISSIBLE FORMAT OF ANSWERS. CIRM WOULD THEN SEND IT TO THE APPLICANT. HERE THIS NEXT BULLET YOU'LL SEE IS A SLIGHT CHANGE FROM THE WRITTEN DOCUMENT. WE'RE SUGGESTING A MAXIMUM TWO WEEKS TO RESPOND, AND THEN THIS WOULD BE CIRCULATED TO THE ENTIRE GRANTS REVIEW GROUP.

WE WERE AFRAID -- IN THE ORIGINAL WE SAID ONE MONTH, BUT THEN WE'RE RUNNING INTO PROBLEMS WITH WHEN THE ICOC WOULD MEET, AND WE DIDN'T WANT TO DELAY THE APPLICATION REVIEW PROCESS. SO WE THOUGHT THESE SHOULD BE QUESTIONS WHERE THEY SHOULD HAVE THE

DATA ALREADY DONE. IT'S NOT A RESEARCH EXPERIMENT THAT THEY COULD THEN GO OUT AND DO. THEY SHOULD HAVE THE DATA IN HAND. THEY JUST DIDN'T PRESENT IT. AND SO THE APPLICANT, WE THOUGHT, HAVING TWO WEEKS IS A REASONABLE AMOUNT OF TIME TO RESPOND.

THERE WOULD THEN BE A TELEPHONIC GRANTS REVIEW GROUP SESSION NO LESS THAN ONE MONTH PRIOR TO THE SCHEDULED ICOC. JUST IN CASE WE CAN'T GET THE ENTIRE GWG BY TELECON, WE WOULD ALLOW A 15-MEMBER QUORUM, WHICH WOULD INCLUDE THE INITIAL PRIMARY AND SECONDARY PEER REVIEWERS, THE KEY SPECIALISTS, THE SCIENTIFIC REVIEW CHAIR, THE GRANT REVIEW GROUP PATIENT ADVOCATE CO-CHAIRS, AND IF ONE IS REPRESENTED ON THE GRANTS REVIEW GROUP, THE PATIENT ADVOCATE FOR THAT SPECIFIC DISEASE. THEN THE GRANTS REVIEW GROUP WOULD MAKE THE RECOMMENDATION, AND THEN THAT WOULD BE PRESENTED TO THE ICOC FOR FINAL DECISIONS.

SO WE FEEL THESE THREE MODIFICATIONS, TWO OF WHICH WE ALREADY CAN DO, THE THIRD OF WHICH WE HAVE NOT YET PILOTED, IS THAT THIS IS PROACTIVE, RAPID, AND COULD FACILITATE A ROBUST YET TIMELY REVIEW OF THE AWARDS, THAT CIRM'S DISEASE TEAM AND CLINICAL TRIAL AWARDS ARE CRITICAL TO CIRM'S MISSION TO ADVANCE THERAPIES AND CURES, THAT IT WOULD BE

FEASIBLE TO IMPLEMENT, PARTICULARLY THIS THIRD MODIFICATION, IF THERE ARE A LIMITED NUMBER OF APPLICATIONS IN WHICH PIVOTAL QUESTIONS ARISE.

THESE MODIFICATIONS IN THE PROCESS BEFORE RECEIPT OF THE APPLICATION, AFTER RECEIPT DURING REVIEW, AND THEN DURING THE GRANTS REVIEW GROUP SESSION WOULD PRESERVE THE KEY ROLE OF SCIENTIFIC PEER REVIEW, PROGRAMMATIC DISCUSSIONS, BUT OUR INTENT IS THAT IT WOULD STRENGTHEN THE FOUNDATION AND THE CERTAINTY IN WHICH RECOMMENDATIONS AND DECISIONS ARE MADE.

AND THAT'S BASICALLY WHAT I WANTED TO PRESENT TO THE BOARD TODAY.

CHAIRMAN THOMAS: COMMENTS? JOAN.

MS. SAMUELSON: I'VE GOT SOME BASIC FACTUAL QUESTIONS BECAUSE IT SEEMS TO ME THIS IS A SET OF MODIFICATIONS THAT AREN'T THE SAME AS THE SET THAT WE REVIEWED, SOME GROUP OF PATIENT ADVOCATES ON THE WORKING GROUP. I'M LOOKING AT JEFF BECAUSE I'M TRYING TO BE REMINDED. AND ESSENTIALLY ALL OF US HAD SIGNIFICANT CONCERNS WITH THAT VERSION. AND I THOUGHT WE WERE GOING TO GET ANOTHER RESPONSE DIRECTLY SO WE COULD CONTINUE COMMUNICATING ABOUT THIS AND TRY TO BE QUICK ABOUT IT, BUT THIS IS SOMETHING DIFFERENT, I THINK.

DR. FEIGAL: I HAVEN'T CHANGED THIS SINCE JUNE.

MR. SHEEHY: JOAN, I THINK THIS IS CONSISTENT WITH WHAT WE WERE WORKING WITH.

MS. SAMUELSON: OKAY.

MR. SHEEHY: AND I THINK STAFF HAS DONE A GREAT JOB HERE ACTUALLY.

MS. SAMUELSON: THEN I'M THINKING OF SOMETHING ELSE.

MR. SHEEHY: I THINK THIS REALLY ADDRESSES -- I THINK THIS CAME OUT. I DON'T WANT TO SAY SHORTCOMING BECAUSE WE WORK VERY HARD IN PEER REVIEW, BUT IT FACILITATES A MORE REAL-TIME ACCESS TO IMPORTANT INFORMATION. I THINK THE ANALOGY THAT OS HAD BROUGHT UP WAS THAT THEY USED TO DO SITE VISITS AT THE NIH. RECOGNIZING THAT THAT'S NOT FEASIBLE, THERE ARE QUESTIONS THAT COME UP THAT COULD BE ANSWERED RELATIVELY EASILY. AND THIS JUST GIVES US THE OPPORTUNITY TO DO THAT. SO I THINK DR. FEIGAL HAS DONE A GREAT JOB OF PULLING THIS TOGETHER. AND WE'VE HEARD THIS IN THE SCIENCE SUBCOMMITTEE.

MS. SAMUELSON: I WAS THINKING OF THE ONE THAT CHANGED PROGRAMMATIC REVIEW.

MR. ROTH: AND I CONCUR. I SAT THROUGH A

NUMBER OF THESE DISCUSSIONS, AND I THINK IT'S A WELL THOUGHT OUT PLAN. IT'S BASED ON OUR EXPERIENCE THAT WE HAD, THINGS THAT DID NOT WORK AND WERE DIFFICULT TO OBTAIN THE INFORMATION THAT WE NEEDED AT THE TIME. THIS ADDRESSES THAT.

WITH THAT, I'D LIKE TO MAKE A MOTION THAT WE APPROVE AS PRESENTED.

CHAIRMAN THOMAS: IS THERE A SECOND?

MS. SAMUELSON: SECOND.

CHAIRMAN THOMAS: SECONDED BY JOAN. FURTHER DISCUSSION? DR. STEWARD.

DR. STEWARD: I'D JUST LIKE TO CONGRATULATE STAFF AGAIN AS WELL BECAUSE I THINK THIS IS JUST AN EXTRAORDINARY WAY TO REALLY GET IT RIGHT. SO OFTEN WE HEAR, WELL, YOU DIDN'T SEE THAT, YOU DIDN'T NOTICE THIS. AND THIS IS A PLACE WHERE WE CAN REALLY BE SURE THAT WE'VE COVERED EVERY BASE AND THAT WE DO THE REVIEW IN THE MOST DILIGENT AND THOROUGH FASHION AND REALLY MAKE SURE THAT THINGS ARE RIGHT AT THE END OF THE DAY. JUST, AGAIN, I REALLY THINK IT'S A GREAT THING. SO THANK YOU.

DR. POMEROY: I THINK THIS IS AN EXAMPLE OF AN INNOVATION THAT MAY BE OF GREAT INTEREST TO OTHER REVIEW AGENCIES GOING FORWARD. AND SO I HOPE THAT MEMBERS OF THE GRANTS WORKING GROUP ALONG WITH

STAFF WOULD CONSIDER A REALLY FORMAL EVALUATION OF THIS PROCESS THAT GETS WRITTEN UP IN THE ACADEMIC LITERATURE BECAUSE I CAN SEE SOME OF THE PEOPLE WHO SUBMIT GRANTS TO THE NIH AND THE NSF GOING I WISH WE HAD THIS OPPORTUNITY WHEN WE WERE SUBMITTING THERE. SO GETTING IT OUT INTO THE LITERATURE WOULD BE A VERY HELPFUL ADDITIONAL STEP.

CHAIRMAN THOMAS: DR. ECONOMOU.

DR. ECONOMOU: I WOULD CONCUR. THERE ARE A LOT OF MOVING PARTS. IT'S GOING TO CREATE MORE WORK FOR THE STAFF, BUT I THINK THIS IS A VERY GOOD PLAN TO ENSURE CONTINUAL PEER REVIEW OF THESE APPLICATIONS THROUGH AN UNBIASED MECHANISM UP TO THE POINT OF IT COMING TO THIS COMMITTEE. I'M LOOKING FORWARD TO SEEING THE BY-PRODUCT OF THAT. THANK YOU.

CHAIRMAN THOMAS: ANY FURTHER COMMENT? PUBLIC COMMENT? HEARING NONE, VOICE VOTE, PLEASE. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? MOTION CARRIES UNANIMOUSLY. THANK YOU, ELLEN.

NEXT ITEM, 12, CONSIDERATION OF THE EXTENSION OF THE RESEARCH LEADERSHIP AWARD PROGRAM. DR. YAFFE.

DR. YAFFE: CHAIRMAN THOMAS, MEMBERS OF THE BOARD, I BRING FOR YOUR CONSIDERATION A REQUEST

FOR AN EXTENSION OF THE APPLICATION PERIOD FOR THE RESEARCH LEADERSHIP AWARDS. THIS IS ITEM NO. 12.

JUST TO REMIND YOU, THE RESEARCH LEADERSHIP AWARDS HAVE AS THEIR GOALS TO FACILITATE THE RECRUITMENT TO CALIFORNIA OF THE MOST PRODUCTIVE AND PROMISING EARLY TO MIDCAREER SCIENTISTS IN STEM CELL BIOLOGY AND REGENERATIVE MEDICINE AND TO SUPPORT, ONCE THESE INDIVIDUALS HAVE BEEN RECRUITED TO CALIFORNIA, TO SUPPORT THEIR ROBUST AND INNOVATIVE RESEARCH PROGRAMS FOCUSED ON FUNDAMENTAL STUDIES OF PLURIPOTENT AND PROGENITOR STEM CELL BIOLOGY AND TRANSLATIONAL STUDIES LEADING TO INNOVATIVE AND STEM CELL-BASED THERAPIES FOR DISEASE AND INJURY.

IN AUGUST 2009 THIS BOARD APPROVED THE CONCEPT AND COMMITTED $44 MILLION TO FUND EIGHT GRANTS TO BE AWARDED OVER A PERIOD OF TWO YEARS. THESE AWARDS FEATURE SIX YEARS OF FUNDING TO SUPPORT INVESTIGATOR SALARY, LAB OPERATIONS, LAB RELOCATION, LABORATORY EQUIPMENT, AND APPROPRIATE INDIRECT AND FACILITY COSTS WITH TOTAL FUNDS FOR EACH AWARD OF UP TO $5.5 MILLION.

THE APPLICATION PROCESS INVOLVES SUBMISSION OF A JOINT APPLICATION, AN APPLICATION FROM THE INSTITUTION AND FROM THE INDIVIDUAL, WITH

APPLICATION REVIEW CYCLES EVERY THREE MONTHS. APPLICATIONS ARE THEN REVIEWED BY THE GRANTS WORKING GROUP, AND THEIR RECOMMENDATION IS BROUGHT TO THIS COMMITTEE WITH FUNDING DECISIONS BY THE ICOC.

THUS FAR TWO GRANTS HAVE BEEN AWARDED TO DATE. ONE TO ROBERT WECHSLER-REYA WHO WAS RECRUITED TO SANFORD BURNHAM INSTITUTE AND A SECOND TO DR. PETER COFFEY, WHO WAS RECENTLY RECRUITED TO UC SANTA BARBARA.

BASED ON THE ORIGINAL TWO-YEAR AUTHORIZED PERIOD FOR THIS PROGRAM, THE LAST SCHEDULED APPLICATION DEADLINE IS NOVEMBER 30, 2011. HOWEVER, RECRUITMENT OF OUTSTANDING SCIENTISTS, THE SCIENTISTS THAT WE'RE LOOKING FOR IN THIS PROGRAM WHO ARE GOING TO BE LEADERS, WHO ARE THE EMERGING LEADERS IN STEM CELL BIOLOGY, IS A VERY CHALLENGING AND LENGTHY PROCESS.

WE UNDERSTAND FROM COMMUNICATION WITH STEM CELL LEADERS AT A NUMBER OF CALIFORNIA INSTITUTIONS THAT RECRUITMENTS ARE UNDER WAY, THAT THEY'VE IDENTIFIED CANDIDATES, AND THEY'RE NOW IN THIS PHASE OF MATING DANCE AND NEGOTIATION TO TRY AND RECRUIT THESE INDIVIDUALS, TO INDUCE THEM TO COME TO CALIFORNIA, SET UP THEIR RESEARCH PROGRAMS, AND EMBARK ON THIS GROUNDBREAKING CONTRIBUTION TO OUR

EFFORTS HERE.

SO WE REQUEST TODAY THAT YOU APPROVE AN EXTENSION OF THE PERIOD OF RECEIPT OF APPLICATIONS FOR THE LEADERSHIP AWARDS PROGRAM FOR AN ADDITIONAL 18 MONTHS BEYOND THE INITIALLY SLATED TWO YEARS. THIS WOULD EXTEND THE PROGRAM APPLICATION PERIOD THROUGH JUNE OF 2013. AND I JUST WANTED TO NOTE THAT NO ADDITIONAL FUNDS ARE REQUESTED.

MR. TORRES: SO MOVED.

DR. YAFFE: THANK YOU.

CHAIRMAN THOMAS: IT'S BEEN MOVED AND SECONDED. IS THERE ANY FURTHER DISCUSSION?

MR. ROTH: SECOND.

DR. LOVE: OBVIOUSLY DR. YAFFE IS A VERY IMPRESSIVE PRESENTER.

CHAIRMAN THOMAS: YES. HE GOT THE PERIPATETIC SENATOR TORRES WHO NO LONGER WANTED TO SIT NEAR TED OR I TO ACTUALLY MOVE BEFORE YOU HAD EVEN FINISHED. THAT'S THE HEIGHT OF PERSUASION.

DR. YAFFE: I WAS PREPARED TO GO ON FOR A FEW.

CHAIRMAN THOMAS: ANY FURTHER DISCUSSION?

MR. SHEEHY: JUST A QUICK QUESTION FOR COUNSEL. THERE'S NO CONFLICT ISSUES HERE? ALL MEMBERS ARE ELIGIBLE TO VOTE?

MR. HARRISON: YES. THIS IS APPROVAL OF THE STANDARD SIMILAR TO THE CONCEPT PLAN APPROVAL ORIGINALLY.

MR. SHEEHY: OKAY.

MS. SAMUELSON: I HAVE A QUESTION. I DON'T KNOW THAT YOU KNOW, BUT HOW MANY APPLICATIONS HAVE WE HAD IN THIS FIRST AUTHORIZED TIME FRAME? I'M NOT -- IT SEEMS LIKE WE HAVEN'T RECEIVED ANY IN THE LAST FEW QUARTERS.

DR. YAFFE: THAT'S CORRECT. BUT WE'VE BEEN TOLD THAT A NUMBER OF CANDIDATES ARE PERCOLATING UP THROUGH THE SYSTEM IN TERMS OF THE NEGOTIATIONS AND RECRUITMENT PROCESSES. AND LEADERS FROM A NUMBER OF THE INSTITUTIONS AND UNIVERSITIES HAVE TOLD US THAT THEY'RE GOING TO SUBMIT WITHIN THE NEXT YEAR. THEY HAVE PARTICULARLY -- THIS REQUEST ORIGINALLY CAME FROM STEM CELL LEADERS AT SEVERAL DIFFERENT CALIFORNIA UNIVERSITIES, WHO SAID THEY WILL HAVE CANDIDATES READY, BUT THEY DID WANT TO -- WE ENCOURAGED THEM TO SUBMIT ONCE THE CANDIDATE REALLY IS PRETTY LOCKED INTO COMING. AND THIS IS A PROTRACTED PROCESS. ACADEMIC RECRUITMENT IS CERTAINLY A CHALLENGING AND FORMIDABLE TASK.

MS. SAMUELSON: JUST ANOTHER QUICK QUESTION. DR. COFFEY DID MOVE FROM GREAT BRITAIN TO

SANTA BARBARA?

DR. YAFFE: WE RECEIVED A LETTER. I DON'T KNOW, ALAN, IF YOU WANTED TO CONFIRM THAT.

DR. TROUNSON: HE'S CONFIRMED TO MOVE TO UC SANTA BARBARA UNDER THE CONDITIONS THAT ARE REQUIRED AT THAT UNIVERSITY. MEETS ALL THE CONDITIONS FOR A FULL-TIME APPOINTMENT THERE. HE WILL HAVE SOME ABILITY TO KEEP CONNECTED WITH HIS WORK IN THE UK, BUT ALL WITHIN THE NORMAL STRUCTURE OF THE UNIVERSITY ALLOWANCES.

DR. YAFFE: WE UNDERSTAND HE WILL BE ON THE GROUND AT THE BENCH IN SANTA BARBARA BY NOVEMBER 1ST.

DR. FINE: THIS IS A TANGENTIAL QUESTION. DO WE HAVE A DATABASE OF THE FLOW OF STEM CELL RESEARCHERS INTO CALIFORNIA OVER THE LAST FIVE YEARS?

DR. YAFFE: WE HAVE CONSIDERABLE INFORMATION. I'M NOT SURE WHAT FORM IT'S IN CURRENTLY. BUT WE KNOW THAT -- I'VE SEEN NUMBERS LIKE 200 OR MORE STEM CELL RESEARCHERS WHO WE PROBABLY COULD IDENTIFY BY NAME WHO HAVE MOVED TO CALIFORNIA.

DR. FINE: HAS THERE BEEN ANY TREND? HAS THERE BEEN ANY FALL-OFF IN THE LAST TWO OR THREE

YEARS AS OTHER AREAS INCREASE THEIR VIABILITY?

DR. YAFFE: I'M NOT AWARE OF THAT.

DR. TROUNSON: THE LAST UPDATES WERE JUST PRIOR TO THE EXTERNAL PANEL REVIEW IN 2010. AND WHAT WE NEED IS TO BE IS ABLE TO GARNER THAT INFORMATION ON AN ONGOING BASIS. SO WE INTEND TO DO THAT. I DON'T THINK THE DYNAMICS OF THE DATA WOULD TELL US WHETHER THERE'S BEEN FLUCTUATIONS UP AND DOWN, BUT IT LOOKS LIKE FAIRLY CONTINUOUS. THERE ARE A FEW PEOPLE WHO'VE ACTUALLY MOVED TO OTHER PLACES, BUT THAT'S A VERY LOW, VERY, VERY LOW PROPORTION OF THE TOTAL MOVEMENT.

CHAIRMAN THOMAS: ON THAT POINT, I THINK IT'S ONE THAT SENATOR TORRES AND I HAVE BEEN TRYING TO DRIVE HOME TO THE GOVERNOR'S OFFICE. AT A TIME WHEN THE STATE IS EXPERIENCING BRAIN DRAIN IN A NUMBER OF OTHER AREAS, THAT THE FACT THAT WE ARE PULLING IN NOT JUST FUTURE EMPLOYEES WORKING IN THE STATE OF CALIFORNIA, BUT HIGHLY QUALIFIED, SKILLED PROFESSIONALS IN THE STEM CELL ARENA IS SOMETHING THAT IS A GREAT RESULT FOR US AND ONE THAT WE'RE ACTIVELY TRUMPETING UP THERE AS THEY ARE FOCUSING MORE AND MORE ON JOBS CREATION AND THAT SORT OF THING.

MS. SAMUELSON: QUESTION, MR. CHAIRMAN.

WOULD IT BE APPROPRIATE TO ASK FOR A BRIEF REVIEW OF THIS, OF THAT FLOW INTO CALIFORNIA AT OUR NEXT MEETING?

CHAIRMAN THOMAS: DR. YAFFE.

MS. SAMUELSON: SORRY TO GIVE YOU MORE WORK.

DR. TROUNSON: THE LAST TIME WE TRIED TO GET THAT INFORMATION, JOAN, WE HAD TO GO SPECIFICALLY TO THE HEADS OF THE STEM CELL UNITS. THIS IS NOT INFORMATION THAT'S EASILY OBTAINED IF YOU WANT TO REALLY GET A GOOD SOUNDING OF IT. SO WE HAVE A MEETING WITH THEM IN A COUPLE OF WEEKS TIME, AND WE'RE GOING TO ASK FOR THEM TO PROVIDE US WITH THAT INFORMATION.

IT DOES TAKE QUITE A BIT OF FOLLOW-UP TO GET IT BECAUSE THEY DON'T HAVE IT SIMPLY IN THEIR DATA OR ON THEIR OFFICE DESK, BUT THEY'RE VERY COMPLIANT ABOUT PROVIDING IT FOR US. AND WE WILL ASK FOR IT IN THE NEXT MEETING, WHICH IS A COUPLE OF WEEKS AWAY. AND HOPEFULLY, IF I THINK IT'S USEFUL, THEN WE'LL BRING IT FORWARD. IF NOT, I'LL WAIT TILL IT IS USEFUL SO THAT WE'VE GOT SOME ACCURACY ABOUT IT.

MS. SAMUELSON: I HAVE INTEREST NOW JUST SPEAKING FOR MYSELF.

CHAIRMAN THOMAS: ANY FURTHER COMMENT BY MEMBERS OF THE BOARD? PUBLIC COMMENT? HEARING NONE, PLEASE EXPRESS AN AYE VOTE IF YOU ARE IN FAVOR. ALL THOSE IN FAVOR SAY AYE. OPPOSED? MOTION CARRIED UNANIMOUSLY. THANK YOU, DR. YAFFE.

DR. YAFFE: THANK YOU.

CHAIRMAN THOMAS: NEXT, ITEM NO. 13, CONSIDERATION OF JOB DESCRIPTION OF CHIEF FINANCIAL OFFICER. MR. GOLDBERG.

MR. GOLDBERG: THANK YOU, CHAIRMAN THOMAS. ON BEHALF OF CHAIRMAN THOMAS AND PRESIDENT TROUNSON, TED LOVE AND I WERE ASKED TO REVIEW THE DUTY STATEMENT, OTHERWISE KNOWN AS A JOB DESCRIPTION, FOR THE CHIEF FINANCIAL OFFICER, WHICH IS UNDER TAB 13.

THAT WAS A DESCRIPTION THAT WAS DEVELOPED BY CHAIRMAN KLEIN AND PRESIDENT TROUNSON OVER THE COURSE OF THE LAST YEAR AND A HALF OR TWO YEARS. AND IT WAS THE ASSIGNMENT OF TED AND I TO CONFER, BASED ON HIS AND MY INDUSTRY EXPERIENCE, AND DEVELOP A CONSENSUS DOCUMENT THAT WAS BOTH ACCEPTABLE TO DR. TROUNSON AND CHAIRMAN THOMAS. WE FOUND THAT TO BE A VERY, VERY STRAIGHTFORWARD AND EASY PROCESS BECAUSE MOST OF THE WORK HAD BEEN DONE BEFORE WE GOT INVOLVED.

GENERALLY I'M ASKED TO PARTICIPATE IN MORE

PROBLEMATIC SITUATIONS. SO THIS WAS, THANKS TO BOTH DR. TROUNSON AND CHAIRMAN THOMAS, A VERY, VERY GRATIFYING EXPERIENCE.

THE MAJOR CONTRIBUTION THAT DR. LOVE AND I MADE WAS THAT IN AN EFFORT TO RECRUIT THE VERY BEST PERSON WE COULD FOR THE POSITION, WE WOULD HAVE TO HAVE VERY, VERY CLEAR REPORTING. THE POSITION IS REALLY A COLLABORATIVE ONE THAT COORDINATES HEAVILY BETWEEN THE PRESIDENT'S OFFICE AND THE CHAIR'S OFFICE, BUT ULTIMATELY IT HAS TO BE A DOTTED LINE RESPONSIBILITY TO ONE AND A SOLID LINE RESPONSIBILITY TO ANOTHER.

AND GIVEN THE DUTIES LAID OUT IN THE JOB DESCRIPTION, AND DR. LOVE AND MY ASSESSMENT OF THE KIND OF CANDIDATES AVAILABLE TO FULFILL SUCH A POSITION, OUR RECOMMENDATION, WHICH WAS ADOPTED BY DR. TROUNSON AND CHAIRMAN THOMAS, WAS TO HAVE THE POSITION REPORTING ON A SOLID LINE BASIS TO THE CHAIR AND A DOTTED LINE BASIS TO THE PRESIDENT WITH A CLEAR UNDERSTANDING THAT IT WOULD BE A POSITION THAT HAD TO INTERACT EFFECTIVELY WITH BOTH THE CHAIRMAN'S OFFICE AS WELL AS THE PRESIDENT'S OFFICE AND THEIR RESPECTIVE STAFFS TO FULFILL ITS RESPONSIBILITIES.

SO WITH THAT, THE DOCUMENT YOU HAVE BEFORE

YOU REPRESENTS OUR COLLECTIVE BEST THINKING, THE FOUR OF US, AND WE WOULD ASK FOR A MOTION TO APPROVE IT SO THAT WE CAN COMMENCE A RECRUITMENT.

MR. TORRES: SO MOVED.

MS. LANSING: SECOND.

CHAIRMAN THOMAS: IT'S BEEN MOVED AND SECONDED. IS THERE ANY DISCUSSION BY MEMBERS OF THE BOARD?

I WOULD LIKE TO THANK MICHAEL AND TED FOR THEIR HELP ON THIS. THIS HAS BEEN A MATTER THAT, AS WAS DULY NOTED, HAS BEEN LINGERING FOR QUITE SOME TIME. THIS ORGANIZATION DESERVES AND NEEDS A CHIEF FINANCIAL OFFICER. ADOPTION OF THIS JOB DESCRIPTION WILL ALLOW FOR IMMEDIATE POSTING AND TO GET THAT SHOW ON THE ROAD. THANK YOU TO THE TWO OF YOU. THANK YOU TO ALAN. I THINK WE'VE GOT A GOOD FINAL PRODUCT HERE.

AND IS THERE ANY PUBLIC COMMENT ON THE SUBJECT? HEARING NONE, THIS IS ANOTHER AYE OR NAY MOTION. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? MOTION CARRIES UNANIMOUSLY.

OUR NEXT ITEM IS AGENDA ITEM 14, CONSIDERATION OF THE REPORT FROM THE INTELLECTUAL PROPERTY SUBCOMMITTEE. I WANT TO SAY THAT OUR NEW CHAIR, STEPHEN JUELSGAARD, CONDUCTED A SUPERB

INAUGURAL MEETING OF THAT SUBCOMMITTEE IN WHICH WE DEALT WITH GREAT MATTERS OF SUBSTANCE WITH REAL SERIOUSNESS AND PURPOSE. AND SO WITH THAT, LET ME TURN IT OVER FOR A REPORT.

DR. JUELSGAARD: THANK YOU, CHAIR THOMAS. IF THAT WERE ONLY TRUE.

SO JUST TO PARAPHRASE KIND OF WHAT HAPPENED LAST EVENING. AND FIRST OF ALL, I WANT TO THANK ALL OF THE SUBCOMMITTEE MEMBERS WHO WERE PRESENT LAST EVENING. I KNOW THAT WAS AN EXTRA BURDEN FOR THOSE OF YOU TO SHOW UP THE EVENING BEFORE THE BOARD MEETING, ESPECIALLY THOSE OF YOU WHO ARE FROM OUT OF TOWN. SO I VERY MUCH APPRECIATED YOUR ABILITY TO MAKE IT TO THE MEETING. IT WAS IMPORTANT FOR ME AT LEAST AS CHAIRMAN OF THE SUBCOMMITTEE TO BE ABLE TO HAVE THAT FIRST MEETING BE IN PERSON WITH AS MANY OF YOU AS POSSIBLE SO THAT WE COULD SORT OF SEE HOW THIS COMMITTEE WILL WORK IN THAT SORT OF A SETTING GOING FORWARD.

THE COMMITTEE DIDN'T TAKE ANY ACTION. WE CONSIDERED OR DISCUSSED THREE ITEMS, TWO OF WHICH I EXPECT THAT WE'LL BRING BACK TO THE OCTOBER MEETING BECAUSE WE HAD SOME GREAT DISCUSSION AROUND THOSE TWO ITEMS, BUT WE NEEDED TO DO A LITTLE BIT FURTHER WORK.

SO THE FIRST WAS REALLY AROUND THE MISSION OF THE SUBCOMMITTEE. AND AS YOU MAY RECALL AT THE LAST BOARD MEETING IN THE CREATION OF THE SUBCOMMITTEE, THERE WAS A MISSION STATEMENT THAT WAS INCLUDED IN THE RESOLUTION. IT WAS A FIVE-PART MISSION STATEMENT, AND WE TOOK A LOOK AT THAT AND DECIDED THAT WE SORT OF DOUBLE-COVERED SOME ITEMS, SO SOME ITEMS COULD BE SUBSUMED INTO WHAT WAS THE MORE GENERAL ITEMS.

WE'RE GOING TO REVISIT THE MISSION STATEMENT AND REVAMP IT A BIT TO DO THAT. IN ADDITION TO THIS, SOMETHING THAT CHAIRMAN THOMAS MENTIONED EARLIER THIS MORNING, TO EXPAND THE SCOPE OF THE SUBCOMMITTEE TO INCLUDE INTERACTIONS WITH INDUSTRY BECAUSE I THINK WE'RE COMING TO A POINT IN THE DEVELOPMENT OF PROJECTS THAT ARE WITHIN THE PURVIEW OF THIS ORGANIZATION WHERE INDUSTRY CAN AND SHOULD PLAY A MORE ACTIVE ROLE GOING FORWARD.

AND WITH THAT, THEN, WE DISCUSSED HAVING DUANE ROTH SERVE AS CHAIR OF THOSE ASPECTS OF THE SUBCOMMITTEE WHILE I WILL SERVE AS CHAIR OF THE INTELLECTUAL PROPERTY ASPECTS, AND WE WOULD EACH SERVE AS VICE CHAIR RESPECTIVELY FOR THOSE TWO ALTERNATE POSITIONS. BUT WE WANT TO DO A LITTLE BIT MORE WORK IN TERMS OF THE LANGUAGE OF THE MISSION

AND AGREE ON IT WITHIN THE SUBCOMMITTEE BEFORE WE COME BACK TO THIS GROUP TO ASK FOR YOUR APPROVAL FOR THAT AS OUR MISSION STATEMENT.

THE SECOND ITEM THAT WE DISCUSSED WAS THE STRATEGIC PARTNERSHIP FUND ASPECT OF THE OPPORTUNITY FUND. SO YOU MAY RECALL THAT THIS BOARD HAS APPROVED $30 MILLION IN FUNDING FOR SOMETHING CALLED THE OPPORTUNITY FUND WHICH HAD SEVERAL DIFFERENT ASPECTS TO IT. AND THE ONE ASPECT THAT WE WERE CHARGED WITH REALLY LOOKING AT WAS AN OPPORTUNITY FUND, SOMETHING THAT WOULD, AGAIN, SPEAK TO INDUSTRY WITH THE POTENTIAL FOR INDUCING THEM TO BECOME MORE INVOLVED PARTICULARLY IN THE CLINICAL RESEARCH STAGE OF PROJECTS.

BUT AS WE DISCUSSED THE OPPORTUNITY FUND, WHICH ELONA BAUM PRESENTED TO US, WE THOUGHT THAT THERE WERE SOME CHANGES TO WHAT WE SAW THERE THAT MIGHT BENEFIT THE PROGRAM. AND WE WANTED TO LOOK A LITTLE FURTHER AT THAT AND SORT OF NAIL THAT DOWN BEFORE WE BROUGHT THAT BACK TO THE BOARD FOR CONSIDERATION, WHICH WE EXPECT TO HAPPEN IN OCTOBER. YOU ALSO NEED TO HAVE A REVIEW BY THE SCIENCE SUBCOMMITTEE OF THE PROPOSAL. SO THAT'S AN INTERVENING ITEM AS WELL.

THEN LASTLY, WE SPOKE ABOUT -- TALKED

BRIEFLY ABOUT THE POTENTIAL FOR AN ASSISTANCE PROGRAM FOR INSTITUTIONS THAT ARE INVOLVED IN CIRM-FUNDED RESEARCH WITH RESPECT TO THE DEVELOPMENT OF THE PROTECTION OF THE INTELLECTUAL PROPERTY THAT THEY DEVELOP. SO THERE'S SORT OF THE TWO DIFFERENT ASPECTS OF THAT. ONE IS SIMPLY FINANCIAL SUPPORT BECAUSE WE UNDERSTAND THAT THERE MAY BE GREATER FINANCIAL NEED AT THIS POINT IN TECHNOLOGY TRANSFER OFFICES, AND WE MIGHT BE ABLE TO PROVIDE SOME ASSISTANCE WITH RESPECT TO THE PROJECTS THAT THIS BODY IS INVOLVED WITH.

AND THERE'S ALSO PERHAPS INSTANCES IN WHICH INSTITUTIONS MIGHT ALSO BENEFIT FROM HELP IN TERMS OF RESOURCES OTHER THAN FINANCIAL RESOURCES. SO IN CONNECTION WITH THAT, THE STAFF IS WORKING ON SETTING UP A MEETING WITH TECHNOLOGY TRANSFER REPRESENTATIVES FROM A NUMBER, AT LEAST SIX DIFFERENT INSTITUTIONS REPRESENTING THE BROAD CROSS SECTION OF ORGANIZATIONS THAT THIS BODY FUNDS TO REALLY TALK TO THEM ABOUT THEIR NEEDS AND WHAT THEY MIGHT FIND USEFUL, ACCEPTABLE, ETC. TO SEE IF THERE IS SOMETHING THAT WE COULD OR SHOULD DO THAT WE COULD THEN, AGAIN, BRING BACK TO THIS BODY FOR CONSIDERATION.

SO THOSE WERE THE THREE TOPICS. I THOUGHT

IT WAS A VERY USEFUL DISCUSSION, AND I THOUGHT THERE WAS A LOT OF GREAT INPUT FROM EVERYBODY INVOLVED.

CHAIRMAN THOMAS: THANK YOU, STEVE. ANY COMMENTS BY MEMBERS OF THE BOARD? MR. GOLDBERG.

MR. GOLDBERG: YES. I JUST WANTED TO SAY THAT I WAS EXTREMELY ENCOURAGED BY STEVE'S LEADERSHIP OF THE COMMITTEE, THE AGENDA, THE DISCUSSION. AND I LOOK FORWARD TO WORKING ON THE NEW COMMITTEE WITH HE AND DUANE UNDER THEIR LEADERSHIP.

CHAIRMAN THOMAS: I FULLY ECHO THAT SENTIMENT.

ANY OTHER COMMENT? ANY PUBLIC COMMENT? OKAY. BELIEVE IT OR NOT --

DR. POMEROY: BEFORE YOU SAY --

MS. LANSING: HERE'S TO EFFICIENCY.

MR. TORRES: HERE. HERE. HERE.

(APPLAUSE.)

DR. POMEROY: I JUST WANTED TO CONGRATULATE AND THANK JON THOMAS FOR A GREAT MEETING. IT WAS WELL ORGANIZED. IT WAS MISSION CRITICAL, MISSION FOCUSED, AND AN IMPRESSIVE DEBUT. SO WE'RE AWFULLY GLAD YOU'RE HERE.

MS. LANSING: I SECOND THAT.

(APPLAUSE.)

CHAIRMAN THOMAS: THANK YOU. THE ORGANIZATION WAS ENTIRELY DUE TO ALL OF YOU. SO I'M JUST HERE TO IMPLEMENT. I WOULD NOTE, BEFORE EVERYBODY GETS UP, TO THE EXTENT ANYBODY IS STILL ON CAMPUS AT FIVE, OVER AT THE STEM CELL INSTITUTE, MANY OF YOU WHO HAVE BEEN OVER THERE HAVE SEEN THAT SPECTACULAR CHANDELIER. THEY ARE AT IRV WEISSMAN'S, I GUESS, COMMISSIONING UNVEILING A SECOND PIECE OF ART, WHICH AT THE MOMENT LOOKS LIKE SOMETHING DRAPED OUT OF PHANTOM OF THE OPERA. BUT THEY'RE HAVING A RECEPTION OVER THERE. SO IF YOU ARE AROUND, THEY WOULD LOVE TO HAVE ANY AND ALL OF US WHO WOULD LIKE TO ATTEND.

DO I HEAR A MOTION TO ADJOURN? 3:23. WE ARE ADJOURNED.

(THE MEETING WAS THEN CONCLUDED AT 3:23 P.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

STANFORD UNIVERSITY
PAUL BERG HALL, LI KA SHING LEARNING CENTER
290 CAMPUS DRIVE
STANFORD, CALIFORNIA
ON
THURSDAY, AUGUST 25, 2011

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
BARRISTER'S REPORTING SERVICE
1072 BRISTOL STREET
SUITE 100
COSTA MESA, CALIFORNIA
(714) 444-4100